

EXHIBIT E

Bruce Alan Rosenzweig, M.D.

Page 353

IN THE COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

-----)	FEBRUARY TERM 2014
IN RE: PELVIC MESH)	
LITIGATION)	
)	
MASTER DOCKET)	NO. 829
-----)	-----
)	
ELLA EBAUGH and)	COURT OF COMMON
MARVIN EBAUGH)	PLEAS
)	
Plaintiffs,)	PHILADELPHIA COUNTY
)	
-vs-)	
)	
ETHICON WOMEN'S HEALTH)	JULY TERM 2013
AND UROLOGY, A DIV. OF)	
ETHICON, INC., ET AL.,)	NO. 00866
)	
Defendants.)	
)	
-----)	

VOLUME II

The resumption of the videotaped de bene esse deposition of BRUCE ALAN ROSENZWEIG, M.D., called for examination, taken before CORINNE T. MARUT, C.S.R. No. 84-1968, Registered Professional Reporter and a Certified Shorthand Reporter of the State of Illinois, at the JW Marriott Chicago, 151 West Adams Street, Chicago, Illinois, on July 15, 2017, commencing at 9:03 a.m.

Bruce Alan Rosenzweig, M.D.

Page 354	Page 356
<p>1 APPEARANCES: 2 ON BEHALF OF THE PLAINTIFFS: 3 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC 4 17 East Main Street, Suite 200 5 Pensacola, Florida 32502 6 850-202-1010 7 BY: DANIEL J. THORNBURGH, ESQ. 8 dthornburgh@awkolaw.com 9 BRAD BRADFORD, ESQ. 10 bbradford@awkolaw.com 11 12 ON BEHALF OF THE DEFENDANTS: 13 BUTLER SNOW LLP 14 500 Office Center Drive, Suite 400 15 Fort Washington, Pennsylvania 19034 16 267-513-1885 17 BY: NILS B. (BURT) SNELL, ESQ. 18 Burt.Snell@butlersnow.com 19 20 BUTLER SNOW LLP 21 1020 Highland Colony Parkway, Suite 1400 22 Ridgeland, Mississippi 39158 23 601-985-4596 24 BY: PAUL S. ROSENBLATT, ESQ. Paul.Rosenblatt@butlersnow.com</p> <p>ALSO PRESENT:</p> <p>RAQUEL LaPOINTE, Paralegal, Anderson Law Offices; THOMAS BODYZIAK, Trial Technician.</p> <p>VIDEOTAPED BY: MILO SAVICH</p> <p>REPORTED BY: CORINNE T. MARUT, C.S.R. No. 84-1968</p>	<p>1 E X H I B I T S (Continued) 2 EXHIBITS PREVIOUSLY MARKED -- FIRST REFERRED TO 3 P1676..... 488 4 P1677..... 510 5 P1962..... 376 6 P2041..... 505 7 P2281..... 630 8 P2282..... 656 9 P2309..... 621 10 P2310..... 636 11 P2321..... 648 12 P2342..... 599 13 P2356..... 626 14 P2362..... 609 15 P2561..... 587 16 P2670..... 513 17 P2684..... 557 18 P2685..... 546 19 P2688..... 519 20 P2691..... 542 21 P2707..... 484 22 P2718..... 476 23 P2719..... 553 24</p>
Page 355	Page 357
<p>1 I N D E X 2 BRUCE ALAN ROSENZWEIG, M.D. EXAMINATION 3 BY MR. THORNBURGH (resumed)... 358 4 5 E X H I B I T S 6 BR-Secur DEPOSITION EXHIBIT MARKED FOR ID 7 No. 6 "Design Defects" slide 438 8 No. 7 C0003, slide 583 9 No. 8 Article by Lim, et al. 592 10 No. 9 Binder containing articles 610 11 relied on by deponent (See 12 First Referred to Exhibits 13 below) 14 15 EXHIBITS PREVIOUSLY MARKED -- FIRST REFERRED TO 16 P0086..... 506 17 P0286..... 382 18 P0290..... 390 19 P0292..... 441 20 P0429..... 358 21 P0523..... 405 22 P0584..... 410 23 P0686..... 444 24 P0706..... 412 P0934..... 524 P0946..... 448 P1008..... 521 P1102..... 424 P1128..... 455 P1185..... 603 P1460..... 569 P1464..... 501</p>	<p>1 THE VIDEOGRAPHER: We are now on the record. 2 My name is Milo Savich and I am the videographer 3 for Golkow Technologies. 4 Today's date is July 15, 2017 and the 5 time is 9:03 a.m. 6 This video deposition is being held in 7 Chicago, Illinois in the matter of Ella 8 Cederberg-Ebaugh vs. Ethicon, Inc., et al., which 9 is being held in the Court of Common Pleas of 10 Philadelphia County, Pennsylvania. The case number 11 is 1307-00866. 12 The deponent is Dr. Bruce Rosenzweig and 13 this is Volume 2 of his deposition. 14 Will counsel please identify themselves 15 for the record. 16 MR. THORNBURGH: Daniel Thornburgh with 17 Aylstock, Witkin, Kreis & Overholtz for the 18 Plaintiffs. 19 MR. SNELL: Burt Snell from Butler Snow for 20 Defendants Ethicon and Johnson & Johnson. 21 MR. ROSENBLATT: Paul Rosenblatt for 22 Defendants Ethicon, Inc. and Johnson & Johnson. 23 MR. BRADFORD: Brad Bradford for the 24 Plaintiffs in the MDL.</p>

2 (Pages 354 to 357)

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 358</p> <p>1 THE VIDEOGRAPHER: The Court Reporter is Corey</p> <p>2 Marut who will now swear in the witness and we may</p> <p>3 then proceed.</p> <p>4 (WHEREUPON, the witness was duly</p> <p>5 sworn.)</p> <p>6 BRUCE ALAN ROSENZWEIG, M.D.,</p> <p>7 called as a witness herein, having been previously</p> <p>8 duly sworn and having testified, was examined and</p> <p>9 testified further as follows:</p> <p>10 DIRECT EXAMINATION (Resumed)</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Good morning, Doctor.</p> <p>13 A. Good morning.</p> <p>14 Q. Did you have a good night's rest?</p> <p>15 A. Yes, sir.</p> <p>16 Q. Good. Doctor, yesterday we went over a</p> <p>17 number of internal documents, and we are going to</p> <p>18 continue to go through Ethicon's corporate</p> <p>19 documents today.</p> <p>20 Is there -- what's the next document in</p> <p>21 your binder that you have selected to discuss with</p> <p>22 the jury today?</p> <p>23 A. P0429.</p> <p>24 Q. And can you identify this exhibit for</p>	<p style="text-align: right;">Page 360</p> <p>1 end of the stick."</p> <p>2 Q. Okay. And, Doctor, can you briefly</p> <p>3 explain to the ladies and gentlemen of the jury</p> <p>4 sort of the situation that occurred in Australia?</p> <p>5 MR. SNELL: Object; form.</p> <p>6 BY THE WITNESS:</p> <p>7 A. This e-mail is from October of 2007.</p> <p>8 Doctors in Australia had voiced concerns about</p> <p>9 their high failure rate and complications</p> <p>10 associated with the TVT-Secur, and their Medical</p> <p>11 Director is communicating that information to other</p> <p>12 Medical Directors and marketing personnel at</p> <p>13 Ethicon worldwide.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Okay. And if you turn with me to</p> <p>16 ETH.MESH.00642330.</p> <p>17 Now, you see that this is an e-mail from</p> <p>18 Aran Maree to a number of other Ethicon employees?</p> <p>19 MR. SNELL: Object; leading.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Correct.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What is this e-mail?</p> <p>24 A. It is an e-mail string, including an</p>
<p style="text-align: right;">Page 359</p> <p>1 the ladies and gentlemen of the jury.</p> <p>2 A. Yes. It is an e-mail string between</p> <p>3 various Medical Directors and marketing personnel</p> <p>4 at Ethicon, including Dr. Aran Maree, who is the</p> <p>5 Medical Director for Ethicon in</p> <p>6 Australia/New Zealand; Dr. Khoo, who was the</p> <p>7 Medical Director Asia Pacific; Dr. Robinson, who is</p> <p>8 the Medical Director; Kevin Mahar from marketing;</p> <p>9 Ted Foltyn from marketing.</p> <p>10 Q. Okay. If you can turn to Exhibit P429</p> <p>11 ETH.MESH number 00642330.</p> <p>12 And before we do, did you review and</p> <p>13 rely on Exhibit -- this exhibit?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And what about Exhibit 429 is</p> <p>16 relevant to your opinions?</p> <p>17 A. Yes. It supports my opinions that</p> <p>18 Ethicon did not do adequate pre-market testing</p> <p>19 prior to launch of the TVT-Secur; that the</p> <p>20 TVT-Secur is, quote-unquote, "device onto itself,"</p> <p>21 therefore the data from the other full-length</p> <p>22 slings is not applicable for the TVT-Secur; and</p> <p>23 that because of the improper pre-market testing,</p> <p>24 that patients, quote-unquote, "received the short</p>	<p style="text-align: right;">Page 361</p> <p>1 e-mail from Dr. Aran Maree, Medical Director for</p> <p>2 Australia and New Zealand, to other Ethicon</p> <p>3 employees, including marketing and Medical</p> <p>4 Directors.</p> <p>5 Q. And what about this e-mail from Aran</p> <p>6 Maree dated October 25, 2007 is relevant to your</p> <p>7 opinion?</p> <p>8 MR. SNELL: Object.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Again, it describes the experience with</p> <p>11 very experienced doctors in Australia and their</p> <p>12 failure rates. They had received training and then</p> <p>13 had received additional training from Dr. Vince</p> <p>14 Lucente, who we had previously talked about, a very</p> <p>15 well-known urogynecologist/pelvic surgeon and a Key</p> <p>16 Opinion Leader.</p> <p>17 Even with the modified technique from</p> <p>18 Dr. Lucente, doctors in Australia that were</p> <p>19 performing the technique were not finding that it</p> <p>20 had improved the results that they were expecting.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. And how is that relevant to your</p> <p>23 opinion?</p> <p>24 A. That is relevant to my opinion that the</p>

Bruce Alan Rosenzweig, M.D.

Page 362	Page 364
<p>1 Instructions for Use is defective and that there</p> <p>2 are design characteristics of the TVT-Secur that</p> <p>3 make it unreasonably unsafe and unreasonably</p> <p>4 ineffective.</p> <p>5 Q. And if we pull up the e-mail on the</p> <p>6 screen, it's from Aran Maree again, as you</p> <p>7 testified, to a number of employees at Ethicon and</p> <p>8 the subject -- what is the subject of this e-mail?</p> <p>9 A. "TVT-O versus TVT-Secur efficacy and</p> <p>10 safety rates."</p> <p>11 Q. Okay. And Dr. Maree writes, "Dear TC</p> <p>12 and Sateesh." Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. It says -- he writes that</p> <p>15 "Following on from my regular Medical Affairs</p> <p>16 update with TC in which I briefed you on matters</p> <p>17 pertaining to Medical Affairs in Australia and</p> <p>18 New Zealand, I want to just reiterate my concerns</p> <p>19 regarding the high failure rates across multiple</p> <p>20 centers that we are seeing with TVT-Secur when</p> <p>21 compared to its predecessor TVT-O."</p> <p>22 Did I read that accurately?</p> <p>23 MR. SNELL: Object; leading, improper direct.</p> <p>24 BY THE WITNESS:</p>	<p>1 Opinion Leader in Australia.</p> <p>2 Q. Okay. And is he -- you say Key Opinion</p> <p>3 Leader. What does that mean?</p> <p>4 A. His -- he is someone whose opinion is</p> <p>5 well respected in the field.</p> <p>6 Q. And do you know whether or not he had</p> <p>7 any relationship with Ethicon?</p> <p>8 A. Yes. If I do recall, that he does have</p> <p>9 a relationship with Ethicon.</p> <p>10 Q. And it says that Malcolm Taylor had</p> <p>11 approximately 20 cases of failure.</p> <p>12 Do you see that?</p> <p>13 MR. SNELL: Objection.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Approximately. Strike that.</p> <p>16 It says Malcolm Taylor approximately 20</p> <p>17 cases failure in approximately 13 cases.</p> <p>18 Do you see that?</p> <p>19 A. That's --</p> <p>20 MR. SNELL: Objection. Hold on. Leading.</p> <p>21 Improper direct. Go ahead.</p> <p>22 BY THE WITNESS:</p> <p>23 A. It's Dr. Malcolm Frazer who --</p> <p>24 BY MR. THORNBURGH:</p>
Page 363	Page 365
<p>1 A. Correct.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And is this what you were summarizing</p> <p>4 just a moment ago?</p> <p>5 A. Yes.</p> <p>6 Q. And he goes on and discusses the</p> <p>7 experience with a number of physicians in</p> <p>8 Australia, is that accurate?</p> <p>9 A. Yes.</p> <p>10 MR. SNELL: Object; leading again.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. And is that what you testified to a</p> <p>13 moment ago?</p> <p>14 MR. SNELL: Objection, leading again.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Correct.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And you see where it says Malcolm --</p> <p>19 "Professor Malcolm Frazer performed"? Do you see</p> <p>20 that part?</p> <p>21 A. Yes.</p> <p>22 Q. And are you aware of from your work in</p> <p>23 this litigation who Dr. Malcolm Frazer is?</p> <p>24 A. Dr. Frazer is a pelvic surgeon and Key</p>	<p>1 Q. Did I say Malcolm Taylor?</p> <p>2 A. Yes.</p> <p>3 Q. Sorry.</p> <p>4 A. Had performed 20 cases and had 13</p> <p>5 failures.</p> <p>6 Q. Okay. So, since I butchered that</p> <p>7 question, what does this document indicate with</p> <p>8 respect to Dr. Malcolm Frazer's experience?</p> <p>9 A. He had performed 20 cases, had 13</p> <p>10 failures and he had performed over 700 of the</p> <p>11 full-length TVT surgeries over the years, so he is</p> <p>12 quite experienced in performing midurethral slings.</p> <p>13 Q. Okay. And also it discusses Bruce --</p> <p>14 Dr. Bruce Farnsworth and Dr. Marcus Carey.</p> <p>15 Do you see that?</p> <p>16 MR. SNELL: Object; leading again.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Correct.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. And are you aware -- do you know who</p> <p>21 Dr. Bruce Farnsworth or Marcus Carey are?</p> <p>22 A. Both Dr. Farnsworth and Dr. Carey are</p> <p>23 well-known pelvic surgeons. Dr. Carey is a Key</p> <p>24 Opinion Leader and has worked and invented pelvic</p>

4 (Pages 362 to 365)

Bruce Alan Rosenzweig, M.D.

Page 366	Page 368
<p>1 floor devices.</p> <p>2 Q. Okay. And what does this document</p> <p>3 indicate with respect to their experience with the</p> <p>4 TVT-Secur product?</p> <p>5 A. They were experiencing lots of early</p> <p>6 failures.</p> <p>7 Q. And if we go to the next paragraph, what</p> <p>8 does the next paragraph indicate with respect to</p> <p>9 how their early failures were addressed by Ethicon?</p> <p>10 A. Well, it states that Dr. Carey had</p> <p>11 trained with Dr. Lucente in the United States and</p> <p>12 was involved with training with two other surgeons;</p> <p>13 that he then used a modified technique from the</p> <p>14 original training as a result of his experience</p> <p>15 early on, but that modified technique still did not</p> <p>16 improve his success rate.</p> <p>17 Q. Okay. And who trained him in the</p> <p>18 modified technique?</p> <p>19 A. Dr. Lucente.</p> <p>20 Q. And who is Dr. Lucente?</p> <p>21 A. As we've discussed before, Dr. Lucente</p> <p>22 is a urogynecologist in the United States, a Key</p> <p>23 Opinion Leader for Ethicon, and very experienced</p> <p>24 surgeon in midurethral slings.</p>	<p>1 A. Yes. The training program was</p> <p>2 inadequate.</p> <p>3 Q. And what's the basis for that opinion?</p> <p>4 A. That doctors were experiencing</p> <p>5 complications and failures from the original</p> <p>6 training. Even after the training was,</p> <p>7 quote-unquote, "modified," doctors were still</p> <p>8 experiencing failures and complications associated</p> <p>9 with the TVT-Secur.</p> <p>10 Q. Is there any other section in this</p> <p>11 e-mail from Aran Maree that is relevant to your</p> <p>12 opinions and, if so, what is the significance of</p> <p>13 that, if any?</p> <p>14 A. This current e-mail from Dr. Aran Maree</p> <p>15 to the -- Dr. Khoo, who is the Medical Director for</p> <p>16 Ethicon in the Asia Pacific, goes on to say that</p> <p>17 "It is the responsibility to ensure that we are</p> <p>18 diligent as a company in performing adequate</p> <p>19 pre-market assessment on multiple dimensions before</p> <p>20 launching the product," which supports my opinion</p> <p>21 that there was inadequate testing in the design and</p> <p>22 development stage prior to launch of the product to</p> <p>23 identify the characteristics of the device that</p> <p>24 made it unreasonably unsafe and unreasonably</p>
Page 367	Page 369
<p>1 Q. Okay. And do you know whether or not</p> <p>2 Dr. Lucente was a paid consultant of Ethicon?</p> <p>3 A. Yes, he was.</p> <p>4 Q. And do you know what Dr. Lucente's role</p> <p>5 was with respect to the TVT-Secur product?</p> <p>6 A. Dr. Lucente was part of the First Human</p> <p>7 Use Study. He was also a proctor, preceptor and</p> <p>8 trainer of surgeons in the -- in how to perform the</p> <p>9 TVT-Secur.</p> <p>10 Q. And do you have any opinion with respect</p> <p>11 to this section of the e-mail that you just</p> <p>12 reviewed with the jury concerning Dr. Lucente and</p> <p>13 the modified technique that he was now using to</p> <p>14 retrain physicians?</p> <p>15 MR. SNELL: Object; leading.</p> <p>16 BY THE WITNESS:</p> <p>17 A. That even with the modified technique,</p> <p>18 doctors were still having the same experience as</p> <p>19 before the modified technique; that there were</p> <p>20 characteristics of the device that made it</p> <p>21 unreasonably unsafe and unreasonably ineffective.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Do you have any opinions one way or the</p> <p>24 other with respect to Ethicon's training program?</p>	<p>1 ineffective.</p> <p>2 Q. And if you look at ETH.MESH again at</p> <p>3 ending in 2330, do you see the concerns that</p> <p>4 Dr. Aran Maree identify?</p> <p>5 MR. SNELL: Object; leading, improper direct</p> <p>6 and expert opinion.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. What concerns did Dr. Aran Maree</p> <p>11 identify that are relevant, if at all, to your</p> <p>12 opinions?</p> <p>13 MR. SNELL: Object.</p> <p>14 BY THE WITNESS:</p> <p>15 A. He states that "the original training</p> <p>16 program may not result in competency in device</p> <p>17 insertion or results in" -- "or result in clinical</p> <p>18 efficacy. There appears to be tricks to insertion</p> <p>19 of the product and removal of the inserters which</p> <p>20 prevent dislodging of the device in the process,</p> <p>21 et cetera."</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. If you look at Concern No. 1.</p> <p>24 MR. THORNBURGH: If we can blow that up really</p>

5 (Pages 366 to 369)

Bruce Alan Rosenzweig, M.D.

Page 370	Page 372
<p>1 quick. Go ahead and highlight that for us, Tom.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. It says, "This product may have been</p> <p>4 launched as a substitute for TVT-O without enough</p> <p>5 clinical data to justify such a rollout."</p> <p>6 Did I read that correctly?</p> <p>7 MR. SNELL: Object; leading as well.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Correct.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Does -- is Dr. Malcolm Taylor's concern</p> <p>12 that he lists in No. 1, is that relevant, if at</p> <p>13 all, to your opinions?</p> <p>14 MR. SNELL: Same objection.</p> <p>15 BY THE WITNESS:</p> <p>16 A. This is actually from Dr. Aran Maree.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. I don't know why I'm saying Taylor. Let</p> <p>19 me strike that.</p> <p>20 With respect to Dr. Aran Maree's</p> <p>21 concerns and specifically Concern No. 1, is that</p> <p>22 significant at all to any of your opinions?</p> <p>23 MR. SNELL: Object and leading again.</p> <p>24 BY THE WITNESS:</p>	<p>1 Do you see that? It goes on to</p> <p>2 page 331?</p> <p>3 MR. SNELL: Object and leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And it says -- it says, "A similar</p> <p>8 recent issue with the Depuy ASR prosthesis resulted</p> <p>9 in an international Safety Alert notice."</p> <p>10 Did I read that correctly?</p> <p>11 MR. SNELL: Object and leading.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Are you aware of the issues that</p> <p>16 Ethicon's company or Johnson & Johnson's company</p> <p>17 Depuy had experienced with respect to its</p> <p>18 prosthetic hip implant?</p> <p>19 MR. SNELL: Object and leading.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Hip prostheses are not my area of</p> <p>22 specialty. I do recall that there were concerns</p> <p>23 regarding lack of long-term stability of the hip,</p> <p>24 which led to the device breaking and complications</p>
Page 371	Page 373
<p>1 A. Yes, this supports my opinions that the</p> <p>2 TVT-Secur device was launched without enough</p> <p>3 clinical data beside the -- there is only the</p> <p>4 five-week, 31 patient Human Use Trial to support</p> <p>5 its safety and efficacy to identify the design</p> <p>6 characteristics that make the device unreasonably</p> <p>7 unsafe and unreasonably ineffective.</p> <p>8 Q. And is -- you had testified at length</p> <p>9 yesterday concerning the lack of adequate testing.</p> <p>10 Is Dr. Aran Maree saying anything</p> <p>11 different than what you have -- had opined to</p> <p>12 yesterday?</p> <p>13 MR. SNELL: Object.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. With respect to -- with respect to the</p> <p>16 clinical data.</p> <p>17 A. No, this supports my opinion that the</p> <p>18 device was rolled out without sufficient clinical</p> <p>19 data to identify the device characteristics that</p> <p>20 make it unreasonably unsafe and unreasonably</p> <p>21 ineffective.</p> <p>22 Q. Aran Maree goes on to say -- it's</p> <p>23 talking about his post-market surveillance</p> <p>24 responsibilities.</p>	<p>1 for patients.</p> <p>2 MR. SNELL: Object. Move to strike. Improper</p> <p>3 undisclosed expert opinion.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And what does Dr. Aran Maree write in</p> <p>6 the next paragraph, first sentence concerning the</p> <p>7 issues that were being experienced at Ethicon,</p> <p>8 Johnson & Johnson and Depuy at that time?</p> <p>9 A. This issue regarding the TVT-Secur --</p> <p>10 MR. SNELL: Object as leading. Sorry.</p> <p>11 Dan, do you want to give me a running</p> <p>12 objection on this document because in Pennsylvania</p> <p>13 you don't walk an expert through a document.</p> <p>14 MR. THORNBURGH: He's already summarized the</p> <p>15 document.</p> <p>16 MR. SNELL: And that's what he does. But now</p> <p>17 you are going through it, which is improper in</p> <p>18 Pennsylvania.</p> <p>19 MR. THORNBURGH: It's not improper. We did</p> <p>20 this --</p> <p>21 MR. SNELL: Were you in Engleman?</p> <p>22 MR. THORNBURGH: I was in Engleman and Adkins.</p> <p>23 MR. SNELL: It didn't happen in Engleman.</p> <p>24 MR. THORNBURGH: It did.</p>

6 (Pages 370 to 373)

Bruce Alan Rosenzweig, M.D.

Page 374	Page 376
<p>1 MR. SNELL: What's the opinion? What's the</p> <p>2 basis? How does it support it?</p> <p>3 MR. THORNBURGH: I was in Engleman.</p> <p>4 MR. SNELL: And you don't move -- well, you're</p> <p>5 leading the expert through it.</p> <p>6 MR. THORNBURGH: You are incorrect. I will</p> <p>7 give you a standing objection. I disagree with</p> <p>8 your position. Go ahead.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Go ahead, Doctor.</p> <p>11 A. "This issue," regarding TVT-Secur, "as</p> <p>12 well as the Depuy ASR issue are reminders that to</p> <p>13 me that our first Credo responsibility to ensure</p> <p>14 that we are diligent as a company performing an</p> <p>15 adequate pre-market assessment on multiple</p> <p>16 dimensions before launching a new product."</p> <p>17 MR. SNELL: Object.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. How, if at all --</p> <p>20 MR. SNELL: Move to strike.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. -- is that statement from Dr. Aran Maree</p> <p>23 relevant to any of your opinions?</p> <p>24 A. Yes, it is.</p>	<p>1 BY THE WITNESS:</p> <p>2 A. Yes, I have an opinion.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. What's that opinion?</p> <p>5 A. That they should put patient safety</p> <p>6 ahead of profit.</p> <p>7 Q. I hand you what's been marked as P1962.</p> <p>8 MR. THORNBURGH: I don't have an unhighlighted</p> <p>9 copy.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Do you recognize Exhibit P1962?</p> <p>12 A. Yes.</p> <p>13 Q. And what is this exhibit?</p> <p>14 A. This is the Credo from</p> <p>15 Johnson & Johnson.</p> <p>16 MR. THORNBURGH: Tom, could you go ahead and</p> <p>17 blow up the first paragraph.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And what is relevant -- what, if</p> <p>20 anything, is relevant to your opinions with respect</p> <p>21 to the Johnson & Johnson Credo?</p> <p>22 MR. SNELL: Object. Object. We will have a</p> <p>23 motion in limine on this for the record. But go</p> <p>24 ahead.</p>
Page 375	Page 377
<p>1 Q. And what's the significance of that</p> <p>2 statement?</p> <p>3 A. That supports my opinions that there was</p> <p>4 inadequate pre-market testing on the device to</p> <p>5 identify characteristics of the device that made it</p> <p>6 unreasonably unsafe and unreasonably ineffective.</p> <p>7 Q. Doctor, have you read -- there is a</p> <p>8 discussion here by Dr. Aran Maree about the Credo</p> <p>9 responsibilities.</p> <p>10 Do you see that?</p> <p>11 A. Yes.</p> <p>12 Q. Are you -- are you aware of what</p> <p>13 Dr. Aran Maree is discussing here with respect to</p> <p>14 the Credo?</p> <p>15 MR. SNELL: Object.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes. The Johnson & Johnson's Credo says</p> <p>18 that their first responsibility is to patients,</p> <p>19 physicians, et cetera.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Doctor, do you have an opinion whether</p> <p>22 or not a company such as Johnson & Johnson should</p> <p>23 put patient safety before profit?</p> <p>24 MR. SNELL: Object.</p>	<p>1 BY THE WITNESS:</p> <p>2 A. That they are stating that their</p> <p>3 responsibility is to doctors, nurses, patients, to</p> <p>4 mothers and fathers and all of those who use our</p> <p>5 products and services.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Do you agree that medical device</p> <p>8 companies like Johnson & Johnson should put patient</p> <p>9 safety first?</p> <p>10 MR. SNELL: Object.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. What are the potential issues, if any,</p> <p>15 for patients if companies who develop medical</p> <p>16 devices don't put patient safety as their top</p> <p>17 priority?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Characteristics of a device that make it</p> <p>21 unreasonably unsafe or unreasonably ineffective are</p> <p>22 not identified and patients end up being harmed by</p> <p>23 those products.</p> <p>24 BY MR. THORNBURGH:</p>

7 (Pages 374 to 377)

Bruce Alan Rosenzweig, M.D.

Page 378	Page 380
<p>1 Q. Okay. And if we turn back to P429. Is</p> <p>2 there anything else in P429 that you want to</p> <p>3 discuss with the ladies and gentlemen of the jury?</p> <p>4 A. Again, this document contains a part of</p> <p>5 an e-mail string from Dr. Khoo, Medical Director of</p> <p>6 Johnson & Johnson Asia Pacific, to Dr. Robinson,</p> <p>7 Medical Director, and Dr. Aran Maree, which agrees</p> <p>8 that devices need to be properly evaluated prior to</p> <p>9 launch so that the patients, quote-unquote, "do not</p> <p>10 receive the short end of the stick," which means</p> <p>11 that patients are not exposed to characteristics of</p> <p>12 a device that are unreasonably unsafe or</p> <p>13 unreasonably ineffective and therefore sustain harm</p> <p>14 from that.</p> <p>15 Q. And you were -- were you referring to a</p> <p>16 specific section in this e-mail string?</p> <p>17 A. Yes. Again from Dr. Khoo to</p> <p>18 Dr. Robinson.</p> <p>19 Q. Can you identify the Bates number for</p> <p>20 the record?</p> <p>21 A. Yes. It ends in 2327.</p> <p>22 MR. THORNBURGH: Tom, go ahead and pull that</p> <p>23 up.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 A. This is an e-mail string from</p> <p>2 October 30, 2007 from the Medical Affairs</p> <p>3 Department in Australia to the Medical Director</p> <p>4 Dr. Aran Maree, Medical Director in</p> <p>5 Australia/New Zealand.</p> <p>6 Q. And what's the significance, if any, of</p> <p>7 Exhibit 1063 with respect to your opinions in this</p> <p>8 case?</p> <p>9 MR. SNELL: Can I get a copy before I hear his</p> <p>10 answer?</p> <p>11 MR. THORNBURGH: Yes.</p> <p>12 MR. SNELL: Give me just one second.</p> <p>13 Only objection, so I have an objection</p> <p>14 on P1063, same as P0429 we just went through with</p> <p>15 regard to other products. The DePuy issue is in</p> <p>16 both of them, and I'm sure that will be part of a</p> <p>17 motion in limine as well as the foreign issue. Go</p> <p>18 ahead.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Okay. Doctor, you had pointed us to</p> <p>21 Exhibit P1063. What, if anything, is significant</p> <p>22 to your opinions from this document?</p> <p>23 A. This document discusses the analysis of</p> <p>24 the data from the TVT-Secur by the Medical Affairs</p>
Page 379	Page 381
<p>1 Q. Okay. What is Dr. Khoo writing to his</p> <p>2 colleague -- colleagues at Ethicon?</p> <p>3 A. "We want to eliminate any possibility of</p> <p>4 product-related issues while considering the</p> <p>5 adequacy of training and what is needed to properly</p> <p>6 roll out a device such that patients receiving them</p> <p>7 do not get the short end of the stick."</p> <p>8 Q. And how is that statement from Dr. Khoo</p> <p>9 relevant or significant to your opinions?</p> <p>10 MR. SNELL: Object.</p> <p>11 BY THE WITNESS:</p> <p>12 A. It supports my opinions that devices</p> <p>13 need to be adequately tested and doctors need</p> <p>14 adequate training on a device to be able to safely</p> <p>15 and properly implant a device so the</p> <p>16 characteristics of the device that are unreasonably</p> <p>17 unsafe or make the device unreasonably ineffective</p> <p>18 are identified prior to it being used in patients.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Okay. Is there -- are you finished with</p> <p>21 Exhibit 429?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. What's the next document that</p> <p>24 you'd like to discuss with the jury?</p>	<p>1 Department in Australia/New Zealand and that the</p> <p>2 assessment is that because of the poor results from</p> <p>3 the data of TVT-Secur, that the marketing tag line</p> <p>4 that it is part of the TVT family and Secur is part</p> <p>5 of that is inappropriate based on the actual</p> <p>6 results from the doctors using the TVT-Secur; that</p> <p>7 it does not function as a treatment for stress</p> <p>8 urinary incontinence as the full-length products in</p> <p>9 the TVT family.</p> <p>10 Q. And --</p> <p>11 MR. SNELL: Object. Move to strike. Go</p> <p>12 ahead.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And is there a specific Bates number</p> <p>15 that you're referencing with respect to that</p> <p>16 opinion?</p> <p>17 A. Yes, it ends in 5447.</p> <p>18 Q. And how is that statement that you --</p> <p>19 from Dr. Aran Maree relevant to your opinions, if</p> <p>20 at all, in this case?</p> <p>21 A. It supports my opinions that the</p> <p>22 TVT-Secur -- the results from the full-length TVT</p> <p>23 devices cannot be used to justify the TVT-Secur's</p> <p>24 performance in efficacy and safety.</p>

8 (Pages 378 to 381)

Bruce Alan Rosenzweig, M.D.

Page 382	Page 384
<p>1 Q. Okay. Is there anything else relevant</p> <p>2 about Exhibit 1063 that you want to discuss with</p> <p>3 the ladies and gentlemen of the jury?</p> <p>4 MR. SNELL: Object.</p> <p>5 BY THE WITNESS:</p> <p>6 A. No.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. What is the next exhibit that you want</p> <p>9 to discuss?</p> <p>10 A. P0286.</p> <p>11 Q. And, again, did you review and rely on</p> <p>12 this exhibit?</p> <p>13 A. Yes.</p> <p>14 Q. Again, just so I don't have to keep on</p> <p>15 saying it --</p> <p>16 MR. SNELL: Can I get --</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. -- did you review and rely on all of the</p> <p>19 exhibits that are in your binder?</p> <p>20 A. Yes.</p> <p>21 MR. SNELL: Thank you.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What about P286 is relevant to your</p> <p>24 opinions?</p>	<p>1 Maree were concerned about in Australia, what, if</p> <p>2 any, action was planned?</p> <p>3 A. That the device would be withdrawn from</p> <p>4 the market in Australia.</p> <p>5 Q. And what does that mean?</p> <p>6 A. That the device would no longer be sold</p> <p>7 to hospitals for doctors to implant it in patients</p> <p>8 to treat stress urinary incontinence.</p> <p>9 Q. And what section of Exhibit P286</p> <p>10 supports that opinion?</p> <p>11 A. Bates stamp 6844.</p> <p>12 MR. THORNBURGH: Tom, if you can pull that up.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And can you direct us to that -- to the</p> <p>15 section you're referencing?</p> <p>16 A. Well, the final conclusion is at the</p> <p>17 bottom of the page under bullet point 3. "We also</p> <p>18 discussed the most appropriate customer-focused and</p> <p>19 Credo-aligned position to take with regard to the</p> <p>20 future use of this product in the Australian</p> <p>21 market. We feel that withdrawing the product from</p> <p>22 the market here is currently the most appropriate</p> <p>23 action for Australia."</p> <p>24 Q. And how -- what is the significance of</p>
Page 383	Page 385
<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. This is an e-mail string that started</p> <p>4 from Dr. Aran Maree, Medical Director of Australia</p> <p>5 and New Zealand, to other key Ethicon employees.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And what, if anything, is significant</p> <p>8 about P286?</p> <p>9 MR. SNELL: Same objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. It supports my opinion that there are</p> <p>12 design characteristics of the TVT-Secur that make</p> <p>13 it unreasonably unsafe and unreasonably effective</p> <p>14 (sic).</p> <p>15 It also supports that -- my opinion that</p> <p>16 the TVT-Secur Instructions for Use are inadequate</p> <p>17 and that even with modified training, doctors</p> <p>18 cannot successfully place the TVT-Secur device and</p> <p>19 that there was inadequate testing during the</p> <p>20 design/development phase before the device was</p> <p>21 launched to be able to identify the characteristics</p> <p>22 of the device that make it unreasonably unsafe or</p> <p>23 unreasonably ineffective.</p> <p>24 Q. To address the issues that Dr. Aran</p>	<p>1 that statement, if any, to your opinions?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. It discusses that the surgeons have</p> <p>5 indicated that their success rate with the</p> <p>6 TVT-Secur is substantially below their success rate</p> <p>7 with other full-length products; that even with the</p> <p>8 modified training, it did not improve their</p> <p>9 results, which demonstrates or supports my opinions</p> <p>10 that there are characteristics of the TVT-Secur</p> <p>11 device that make it unreasonably ineffective to</p> <p>12 treat stress urinary incontinence and have</p> <p>13 characteristics that make it unreasonably unsafe.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. And do you have an opinion one way or</p> <p>16 the other with respect to the potential action</p> <p>17 that's being discussed by Dr. Aran Maree concerning</p> <p>18 withdrawing the TVT-Secur from the market in</p> <p>19 Australia?</p> <p>20 MR. SNELL: Object and leading.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Yes. There is a further discussion from</p> <p>23 members of the Ethicon/Johnson & Johnson corporate</p> <p>24 office, including the president of</p>

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 386</p> <p>1 Johnson & Johnson, Renee Selman, that if this</p> <p>2 information regarding Australia removing the</p> <p>3 TVT-Secur from the market could cause problems in</p> <p>4 other areas of the world.</p> <p>5 MR. SNELL: Object. Move to strike.</p> <p>6 Non-responsive. Reading document.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And where -- what part of Exhibit 286</p> <p>9 supports that opinion?</p> <p>10 A. P6842.</p> <p>11 Q. And you discussed, I think you mentioned</p> <p>12 Renee Selman. Again, can you remind the jury who</p> <p>13 Renee Selman is?</p> <p>14 A. She's the president of Johnson & Johnson</p> <p>15 and this is from Catherine Beath, who is in</p> <p>16 regulatory at Johnson & Johnson.</p> <p>17 Q. And --</p> <p>18 MR. SNELL: Object. Move to strike.</p> <p>19 Misstates the evidence.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. And do you -- there are some other</p> <p>22 individuals that are on this e-mail, this e-mail</p> <p>23 string with Renee Selman. Can you identify who</p> <p>24 those folks are?</p>	<p style="text-align: right;">Page 388</p> <p>1 Aran Maree is the -- who is Aran Maree</p> <p>2 again?</p> <p>3 MR. SNELL: Object.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Medical Director of</p> <p>6 Australia/New Zealand.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And Sheri McCoy and Renee Selman, where</p> <p>9 are they located?</p> <p>10 A. At the corporate office in, if I recall,</p> <p>11 in New Jersey.</p> <p>12 Q. So, they are the United States</p> <p>13 executives?</p> <p>14 A. Correct.</p> <p>15 MR. SNELL: Object; leading.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Okay. And do you have any opinion with</p> <p>18 respect to the concerns that you just discussed</p> <p>19 that are being raised by Sheri McCoy in this</p> <p>20 document?</p> <p>21 MR. SNELL: Object and leading.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Can you repeat the question, please.</p> <p>24 BY MR. THORNBURGH:</p>
<p style="text-align: right;">Page 387</p> <p>1 MR. SNELL: Leading.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Sheri McCoy, who is from the corporate</p> <p>4 office at Johnson & Johnson. Mark Yale, if I</p> <p>5 recall, is a safety officer at Johnson & Johnson.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And what concerns, if any, were being</p> <p>8 discussed between these Ethicon employees?</p> <p>9 MR. SNELL: Object. Leading as well.</p> <p>10 BY THE WITNESS:</p> <p>11 A. The marketing problems that would happen</p> <p>12 around the world if the information about Australia</p> <p>13 removing the product from the market were made</p> <p>14 known on an international basis.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Now, when you were practicing -- as a --</p> <p>17 strike that.</p> <p>18 As a practicing urogynecologist in</p> <p>19 November of 2007 or after, were you ever made aware</p> <p>20 of the issues that are being discussed within these</p> <p>21 exhibits concerning Australia?</p> <p>22 A. No.</p> <p>23 Q. And just to sort of briefly summarize</p> <p>24 these two documents.</p>	<p style="text-align: right;">Page 389</p> <p>1 Q. Yeah. Do you have any opinions with</p> <p>2 respect to the concerns of Sheri McCoy that you</p> <p>3 identified earlier on Bates No. 6842?</p> <p>4 MR. SNELL: Object and leading.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Well, I have an opinion that Dr. Maree</p> <p>7 made the right decision about removing the</p> <p>8 TVT-Secur from the Australian and New Zealand</p> <p>9 market, and I agree with the statement that was</p> <p>10 made that this would absolutely cause problems in</p> <p>11 other areas of the world.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Do you have any --</p> <p>14 MR. SNELL: Move to strike. Non-responsive.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Do you have any opinions with respect to</p> <p>17 what actions could have been taken by</p> <p>18 Ethicon/Johnson & Johnson to alert physicians in</p> <p>19 the United States concerning these issues?</p> <p>20 MR. SNELL: Object.</p> <p>21 BY THE WITNESS:</p> <p>22 A. A letter could be sent to doctors</p> <p>23 regarding the action that was being taken in</p> <p>24 Australia regarding the TVT-Secur product.</p>

Bruce Alan Rosenzweig, M.D.

Page 390	Page 392
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And did that ever happen?</p> <p>3 A. No.</p> <p>4 MR. SNELL: Same objection.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. And by "letter," are you referring --</p> <p>7 what type of letter should be sent?</p> <p>8 MR. SNELL: Same objection.</p> <p>9 BY THE WITNESS:</p> <p>10 A. A Dear Doctor letter.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Okay. And what's the next exhibit that</p> <p>13 you want to discuss?</p> <p>14 A. P0290.</p> <p>15 Q. And what, if anything, from Exhibit 290</p> <p>16 is significant to your opinions?</p> <p>17 A. This is --</p> <p>18 MR. SNELL: Object. Go ahead.</p> <p>19 BY THE WITNESS:</p> <p>20 A. This is an e-mail string between</p> <p>21 Dr. Aran Maree and other Ethicon employees in</p> <p>22 Australia and New Zealand. Ultimately it is copied</p> <p>23 to Dr. Robinson and Mark Yale.</p> <p>24 It supports my opinions that the</p>	<p>1 that this isn't training. "This is how things</p> <p>2 should have been," the re-training that was done,</p> <p>3 "This is how things should have been done and how</p> <p>4 we should" -- "how we always should have been</p> <p>5 trained. Also nuances I have been learning over</p> <p>6 the last two weeks were never what I thought in the</p> <p>7 beginning. Even so, he is not yet," with regard to</p> <p>8 Dr. Frazer, "convinced that even with these changes</p> <p>9 the device is going to be successful as the other</p> <p>10 full-length devices and I haven't seen enough</p> <p>11 evidence. Even Vince Lucente's data is not</p> <p>12 convincing to me...and that the TVT-Secur device is</p> <p>13 so utterly different to the other TVT devices that</p> <p>14 it should not be called a TVT and the speed to</p> <p>15 market and the breadth of the launch did not take</p> <p>16 this into account."</p> <p>17 MR. SNELL: Object. Move to strike. Reading.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And if you turn to page 061 that you had</p> <p>20 referenced earlier.</p> <p>21 MR. THORNBURGH: Tom, go ahead and pull up</p> <p>22 little (i), section (i). Section 1.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. And this says, "Regarding the</p>
Page 391	Page 393
<p>1 TVT-Secur device is a different -- is such a</p> <p>2 different device from the other full-length slings</p> <p>3 that the data from the other full-length slings</p> <p>4 cannot be used to justify the TVT-Secur.</p> <p>5 It supports my opinions that the</p> <p>6 Instructions for Use were defective because they</p> <p>7 were fundamentally misleading and that the training</p> <p>8 on the TVT-Secur was inadequate.</p> <p>9 Q. And can you direct us to the portions of</p> <p>10 this exhibit that support your opinions?</p> <p>11 A. Yes. On ETH.MESH.7062.</p> <p>12 Q. And what part of that page supports your</p> <p>13 opinion?</p> <p>14 A. Actually, it starts on ETH.MESH.7061 and</p> <p>15 continues to the next page.</p> <p>16 Dr. Maree, again, the Medical Director</p> <p>17 Australia/New Zealand, is writing regarding the</p> <p>18 Instructions for Use.</p> <p>19 Dr. Frazer said it is his opinion that</p> <p>20 the Instructions for Use is fundamentally</p> <p>21 misleading. "He described the blue diagrams as</p> <p>22 'confusing' and 'contradictory or confusing</p> <p>23 statements on tension.'"</p> <p>24 Dr. Frazer also discussed with Dr. Maree</p>	<p>1 Instructions for Use (IFU), Professor Frazer said</p> <p>2 that this is his opinion that 'the IFU,'" and this</p> <p>3 is in quotes, "the IFU is fundamentally</p> <p>4 misleading. Tension-free, tension-less and</p> <p>5 placement with no tension are complete misnomers."</p> <p>6 Did I read that correctly?</p> <p>7 MR. SNELL: Object and leading.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Yes.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And this is the section of the -- this</p> <p>12 exhibit that you had directed us to?</p> <p>13 MR. SNELL: Object and leading.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Correct.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And how does this section support your</p> <p>18 opinion?</p> <p>19 MR. SNELL: Object.</p> <p>20 BY THE WITNESS:</p> <p>21 A. It supports my opinion that the IFU is</p> <p>22 defective.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Okay. And if we go to Section (iii),</p>

11 (Pages 390 to 393)

Bruce Alan Rosenzweig, M.D.

Page 394	Page 396
<p>1 Dr. Maree writes, "Regarding the revised Key 2 Technical Points document." 3 Do you see that? 4 A. Yes. 5 Q. What is the Key Technical Points 6 document? 7 A. That would be the cookbook that we 8 discussed earlier. 9 Q. It says, "Regarding the revised Key 10 Technical Points document, he said," referring to 11 Dr. Frazer, "that 'the section on tension-free is 12 inadequate' in his opinion. It is 'still not as 13 clear as it could be.' He described the blue 14 diagram as 'confusing' and said there appeared to 15 be 'contradictory or confusing statements on 16 tension' within the body of the text." 17 Did I read that correctly? 18 MR. SNELL: Object and leading. 19 BY THE WITNESS: 20 A. Yes. 21 BY MR. THORNBURGH: 22 Q. How does that section support your 23 opinion, if at all? 24 MR. SNELL: Object; leading.</p>	<p>1 Q. And do you have an opinion as to why 2 that -- the cookbook could not address or did not 3 address the issues of failure? 4 MR. SNELL: Object. 5 BY THE WITNESS: 6 A. Because the device has characteristics 7 that make it unreasonably ineffective and 8 unreasonably unsafe and the Instructions for Use is 9 defective in describing how to place the device. 10 BY MR. THORNBURGH: 11 Q. When you say "because the device has 12 characteristics that make it unreasonably 13 ineffective and unreasonably unsafe," what do you 14 mean by that? 15 A. One of the characteristics that makes it 16 unreasonably ineffective is that the fleece tips 17 that are used to hold the device into place to give 18 midurethral support are ineffective in doing that 19 because they are defectively designed. 20 The stiffness of the mesh being short 21 and laser-cut is -- has characteristics that had 22 been shown to make the smooth muscle of the urethra 23 not function as well, which makes either the 24 incontinence difficult to treat or will lead to a</p>
Page 395	Page 397
<p>1 BY MR. THORNBURGH: 2 Q. Let me ask a better question. 3 What, if anything, is significant about 4 that statement? 5 MR. SNELL: Objection. 6 BY THE WITNESS: 7 A. It supports my opinions that the 8 Instructions for Use is misleading and misleading 9 on the section on how to tension the device; that 10 the concept of tension-free, which we described 11 earlier is on the box, "Tension-free support for 12 incontinence," is inaccurate. 13 BY MR. THORNBURGH: 14 Q. Doctor, yesterday you talked a little 15 bit about and offered opinions about the cookbook. 16 Do you recall that? 17 A. Yes. 18 Q. Did -- does it appear from this exhibit, 19 this internal company document, that the cookbook 20 addressed the issues with the TVT-Secur? 21 MR. SNELL: Object; leading. 22 BY THE WITNESS: 23 A. It did not. 24 BY MR. THORNBURGH:</p>	<p>1 recurrence of incontinence. 2 The sharp arrow tip introducer drags 3 across vaginal tissue, which disrupts the vaginal 4 tissue, which will make the device either cause a 5 complication, therefore, making it unreasonably 6 unsafe, or will lead to a recurrence of 7 incontinence or not treat the incontinence to begin 8 with, making it unreasonably ineffective. 9 Q. And if we look at the next section, 10 Section (iv), it says, "Regarding re-training on 11 key points, Professor Frazer said that he disagreed 12 with the company calling it re-training." 13 And then he's quoted as saying, "This 14 isn't re-training. This is how things always 15 should have been done and how we always should have 16 been trained." 17 Do you see that? 18 A. Yes. 19 MR. SNELL: Object and leading. 20 BY MR. THORNBURGH: 21 Q. Do you have any opinions with respect to 22 that statement from Dr. Frazer? 23 MR. SNELL: Object and leading. 24 BY THE WITNESS:</p>

12 (Pages 394 to 397)

Bruce Alan Rosenzweig, M.D.

Page 398	Page 400
<p>1 A. Yes. That supports my opinions that the</p> <p>2 training given to doctors was inadequate and that</p> <p>3 the Instructions for Use is defective.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And he goes on to say also in quotes,</p> <p>6 "The nuances I have been learning in the last two</p> <p>7 weeks were never what I was taught in the</p> <p>8 beginning.' Even so, he is 'not yet convinced,'"</p> <p>9 referring to Dr. Lucente -- or referring to</p> <p>10 Dr. Frazer -- "not yet convinced that even with</p> <p>11 these changes the device is going to be as</p> <p>12 successful as TVT-O and TVT Retropubic."</p> <p>13 Did I read that correctly?</p> <p>14 MR. SNELL: Object and leading.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And what, if anything, about that</p> <p>19 statement is significant to your opinions?</p> <p>20 MR. SNELL: Same objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. That there are characteristics of the</p> <p>23 device that make it unreasonably ineffective.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 paragraph on Bates number ending in 062, it says,</p> <p>2 discussing Professor Frazer, "that he still thinks</p> <p>3 Ethicon 'does uro-gyne better than other companies'</p> <p>4 but that TVT-Secur is so 'utterly different to the</p> <p>5 other TVTs that it probably shouldn't be called a</p> <p>6 TVT' and the speed to market and the breadth of the</p> <p>7 launch did not take this into account, thus</p> <p>8 requiring all this subsequent follow-up activity."</p> <p>9 Did I read that correctly?</p> <p>10 MR. SNELL: Object and leading.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And -- what, if anything, about that</p> <p>15 section or statement in this document supports your</p> <p>16 opinion?</p> <p>17 MR. SNELL: Same objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. It supports my opinion that the data</p> <p>20 from the other full-length TVT products cannot be</p> <p>21 used to justify the TVT-Secur and that the</p> <p>22 design/development and the rush to market was</p> <p>23 inadequate to identify characteristics of the</p> <p>24 device that make it unreasonably unsafe or</p>
Page 399	Page 401
<p>1 Q. And it goes on to say, "I haven't yet</p> <p>2 seen enough evidence. Even Vince Lucente's data</p> <p>3 isn't yet convincing to me."</p> <p>4 Do you see that?</p> <p>5 A. Yes.</p> <p>6 MR. SNELL: Objection; leading.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And we discussed Dr. Lucente's data</p> <p>9 yesterday. Do you recall that?</p> <p>10 MR. SNELL: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Correct.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And was Dr. Lucente's data convincing</p> <p>15 that the re-training or the new techniques or the</p> <p>16 learning curve would resolve the issues with the</p> <p>17 TVT-Secur device?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. And then you talked about the device</p> <p>23 being utterly different than other TVTs. If you --</p> <p>24 if I can direct your attention to the last</p>	<p>1 unreasonably ineffective.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And is this statement -- these aren't</p> <p>4 your words, are they?</p> <p>5 A. No.</p> <p>6 Q. Are these statements within Ethicon's</p> <p>7 own document, which are being made by Dr. Frazer or</p> <p>8 Dr. Aran Maree, consistent with your opinions?</p> <p>9 MR. SNELL: Objection and leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Now, I want to turn your attention to</p> <p>14 page -- the first page on Exhibit 290.</p> <p>15 Do you see where -- what does Dr. --</p> <p>16 strike that.</p> <p>17 What does Dr. Robinson write to Dave --</p> <p>18 sorry.</p> <p>19 What does Dr. Robinson write to Mark</p> <p>20 Yale?</p> <p>21 MR. SNELL: Object and leading now.</p> <p>22 BY THE WITNESS:</p> <p>23 A. "Thanks for the follow-up. We will</p> <p>24 ultimately need to discuss Instructions for Use</p>

Bruce Alan Rosenzweig, M.D.

Page 402	Page 404
<p>1 suggestions."</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Now, do you have an opinion whether or</p> <p>4 not the TVT-Secur IFU was, as using the words of</p> <p>5 Dr. Frazer, was fundamentally misleading?</p> <p>6 MR. SNELL: Object and leading.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And what's that opinion?</p> <p>11 A. That the Instructions for Use were</p> <p>12 defective fundamentally and misleading is -- and an</p> <p>13 indication that the Instructions for Use were</p> <p>14 defective.</p> <p>15 Q. Now, with respect to David Robinson's</p> <p>16 statement here that he and Mark would ultimately</p> <p>17 need to discuss the IFU suggestions, do you know</p> <p>18 whether or not Ethicon ever made any changes to its</p> <p>19 IFU?</p> <p>20 A. They did not.</p> <p>21 Q. And do you have an opinion whether or</p> <p>22 not -- strike that.</p> <p>23 Is that significant in any way to your</p> <p>24 opinion?</p>	<p>1 medical literature that we are discussing.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Now, ultimately what happened in</p> <p>4 Australia?</p> <p>5 A. The --</p> <p>6 MR. SNELL: Object.</p> <p>7 BY THE WITNESS:</p> <p>8 A. The TVT-Secur was removed from the</p> <p>9 market.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Did Ethicon or Johnson & Johnson</p> <p>12 withdraw the TVT-Secur from the U.S. market?</p> <p>13 A. In 2012.</p> <p>14 Q. If the problems with the TVT-Secur were</p> <p>15 isolated only to Australia, why, in your opinion,</p> <p>16 would Ethicon pull the product from the market in</p> <p>17 the United States in 2012?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. There are a number of internal documents</p> <p>21 and medical literature that shows that the</p> <p>22 characteristics of the TVT-Secur device that made</p> <p>23 it unreasonably unsafe or unreasonably ineffective</p> <p>24 were not just discovered in Australia.</p>
Page 403	Page 405
<p>1 A. Yes.</p> <p>2 Q. In what way?</p> <p>3 A. If the Instructions for Use is</p> <p>4 defective, it should be modified to find out the</p> <p>5 characteristics of the Instructions for Use that</p> <p>6 make it defective and thereby corrected or, if it</p> <p>7 cannot be remedied, remove the product from the</p> <p>8 market.</p> <p>9 Q. Do you have an opinion whether or not</p> <p>10 the IFU could have been remedied in a way that</p> <p>11 would have made the TVT-Secur safe?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I do have an opinion.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. What's that opinion?</p> <p>17 MR. SNELL: Same. Carry on.</p> <p>18 BY THE WITNESS:</p> <p>19 A. It could not.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. What's the basis for that opinion?</p> <p>22 MR. SNELL: Same.</p> <p>23 BY THE WITNESS:</p> <p>24 A. All of the internal documents and the</p>	<p>1 MR. SNELL: Object. Move to strike as</p> <p>2 non-responsive.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. I'm going to hand you -- what's the next</p> <p>5 document that you want to discuss with the ladies</p> <p>6 and gentlemen of the jury?</p> <p>7 A. P0523.</p> <p>8 Q. And what is significant with respect</p> <p>9 to -- strike that.</p> <p>10 Did you review and rely on P523?</p> <p>11 A. Yes.</p> <p>12 Q. And can you identify what this document</p> <p>13 is for the ladies and gentlemen of the jury?</p> <p>14 MR. SNELL: Before you -- let me just look at</p> <p>15 it real quickly. Thank you.</p> <p>16 BY THE WITNESS:</p> <p>17 A. It is an e-mail string starting from</p> <p>18 Jonathan Meek, key Ethicon employee, to Renee</p> <p>19 Selman who we have identified as the president of</p> <p>20 Johnson -- excuse me -- of Ethicon and continued to</p> <p>21 other key Ethicon personnel and Medical Directors.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Okay. And what about Exhibit 523 is</p> <p>24 significant, if anything, to your opinion?</p>

Bruce Alan Rosenzweig, M.D.

Page 406	Page 408
<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. It's discussing Dr. Aran Maree's</p> <p>4 decision in Australia/New Zealand and that this</p> <p>5 will likely -- the likely outcome will be a safety</p> <p>6 warning letter that will be recommended and cascade</p> <p>7 around the world.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Okay. Now, based upon your review of</p> <p>10 Ethicon's documents, internal documents, did you</p> <p>11 see any evidence that Ethicon or Johnson & Johnson</p> <p>12 ever sent a Dear Doctor letter to U.S.,</p> <p>13 United States, doctors?</p> <p>14 A. Regarding what was going on in Australia</p> <p>15 and New Zealand?</p> <p>16 Q. With respect to either what was going on</p> <p>17 in Australia or New Zealand or with respect to the</p> <p>18 experiences that doctors around the world were</p> <p>19 having with the TVT-Secur device?</p> <p>20 MR. SNELL: Object.</p> <p>21 BY THE WITNESS:</p> <p>22 A. In November of 2007, no.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Did you see any evidence that based</p>	<p>1 Q. Do you have an opinion about whether or</p> <p>2 not Dr. Aran Maree's action of withdrawing the</p> <p>3 TVT-Secur from the market in Australia and</p> <p>4 New Zealand was appropriate?</p> <p>5 MR. SNELL: Objection and leading.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes, I do have an opinion.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. What's that opinion?</p> <p>10 MR. SNELL: Same.</p> <p>11 BY THE WITNESS:</p> <p>12 A. It was an appropriate decision.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Do you have any understanding as to why</p> <p>15 Renee Selman or Sheri McCoy didn't make the same</p> <p>16 recommendations in the United States?</p> <p>17 MR. SNELL: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I do not, but the prior document that we</p> <p>20 looked at was discussing -- discussing marketing</p> <p>21 implications.</p> <p>22 MR. SNELL: Move to strike after "I do not."</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. What marketing implications are being</p>
Page 407	Page 409
<p>1 on -- strike that.</p> <p>2 Based on your review of Ethicon's</p> <p>3 documents, did you see any evidence that Ethicon</p> <p>4 ever sent a Dear Doctor letter to U.S. doctors?</p> <p>5 A. If I recall, there was a letter that was</p> <p>6 sent to doctors in 2012.</p> <p>7 Q. And what did that -- and what was that</p> <p>8 related to?</p> <p>9 A. The discussion of removing the TVT-Secur</p> <p>10 from the market in the United States.</p> <p>11 Q. Do you have an opinion whether or not</p> <p>12 Ethicon should have sent a letter to doctors in the</p> <p>13 United States, or worldwide for that matter,</p> <p>14 sometime before 2012?</p> <p>15 A. Yes.</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. What's that opinion?</p> <p>19 MR. SNELL: Same objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. That the discussion in November of 2007</p> <p>22 that I agree that a letter should have,</p> <p>23 quote-unquote, "cascaded around the world."</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 discussed, Doctor?</p> <p>2 A. The negative impact of removal of the</p> <p>3 TVT-Secur from the Australian and New Zealand</p> <p>4 marketplace, the negative impact that would have on</p> <p>5 marketing worldwide.</p> <p>6 Q. And by "marketing," do you mean</p> <p>7 continuing to sell the product so that Ethicon and</p> <p>8 Johnson & Johnson can continue to make a profit?</p> <p>9 MR. SNELL: Objection and leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Correct.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. In Australia did Aran Maree put patient</p> <p>14 safety above profit?</p> <p>15 MR. SNELL: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. In the United States, do you have an</p> <p>20 opinion whether or not Sheri McCoy or Renee Selman</p> <p>21 put patient safety above making a profit?</p> <p>22 MR. SNELL: Objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I do have an opinion.</p>

15 (Pages 406 to 409)

Bruce Alan Rosenzweig, M.D.

Page 410	Page 412
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. What's that opinion?</p> <p>3 MR. SNELL: Same.</p> <p>4 BY THE WITNESS:</p> <p>5 A. They put profit above patient safety.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. What's the next document you'd like to</p> <p>8 discuss with the ladies and gentlemen of the jury?</p> <p>9 A. P0584.</p> <p>10 Q. And what about P0584 is relevant to your</p> <p>11 opinions in this case?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. It supports my opinions about the design</p> <p>15 characteristics of the TVT-Secur that make it</p> <p>16 unreasonably unsafe and unreasonably ineffective.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Okay. And just identify for the record</p> <p>19 what P584 is.</p> <p>20 A. It is an e-mail string between -- from</p> <p>21 November 26, 2007 from Dan Smith to Mark Yale. The</p> <p>22 subject is "TVT-Secur update."</p> <p>23 Q. And what section of P584 are you</p> <p>24 referring to?</p>	<p>1 to P706.</p> <p>2 MR. SNELL: On P0584 just note MIL, foreign</p> <p>3 regulatory discussions, TGA, as well as Australia</p> <p>4 issue.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Doctor, can you identify what P706 is</p> <p>7 for the ladies and gentlemen of the jury?</p> <p>8 A. Yes. This is an internal Ethicon</p> <p>9 document. It is a PowerPoint presentation from the</p> <p>10 Quality Board. If I recall, this is from 2008.</p> <p>11 Q. And did you review and rely on P706?</p> <p>12 A. Yes.</p> <p>13 Q. And what, if anything, is significant</p> <p>14 from this document and what opinions does it</p> <p>15 support?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY THE WITNESS:</p> <p>18 A. This document supports my opinions that</p> <p>19 there was inadequate training of the TVT-Secur</p> <p>20 device; that the Instructions for Use were</p> <p>21 defective; and that there are design</p> <p>22 characteristics of the TVT-Secur that make it</p> <p>23 unreasonably unsafe and unreasonably ineffective.</p> <p>24 BY MR. THORNBURGH:</p>
Page 411	Page 413
<p>1 A. The need to further -- "need for further</p> <p>2 data to look" -- "to be looked at before and after</p> <p>3 revised tips and tricks documents to see how</p> <p>4 effective it is in regions of the world. Question</p> <p>5 to be answered is Australia different from the rest</p> <p>6 of the world or is it possibly" -- "or is this</p> <p>7 possible extension of issues in Germany."</p> <p>8 MR. SNELL: Object. Move to strike. Reading.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And how is Exhibit P84 (sic) relevant to</p> <p>11 your opinions in this case?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. P -- this e-mail string is important for</p> <p>15 my opinions that this was not just an isolated</p> <p>16 occurrence of problems. This is documenting the</p> <p>17 design characteristics of the TVT-Secur that made</p> <p>18 it unreasonably unsafe and unreasonably</p> <p>19 ineffective.</p> <p>20 This was not just isolated to Australia,</p> <p>21 but this was experience that was seen around the</p> <p>22 world.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Okay. If we can look at P -- let's go</p>	<p>1 Q. And can you just walk us through</p> <p>2 Exhibit 706 identifying which slides you are</p> <p>3 relying on and how the information on those slides</p> <p>4 support your opinions.</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes. Page 10 of the document is called</p> <p>8 "Revised Training."</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Okay. And what about page 10 is</p> <p>11 significant to your opinions?</p> <p>12 A. Well, this document demonstrates that</p> <p>13 re-training was not just isolated to Australia or a</p> <p>14 single other country; that re-training was</p> <p>15 happening in the United States, Germany, Finland,</p> <p>16 showing that this was a -- the defects in the</p> <p>17 Instructions for Use and the design characteristics</p> <p>18 of the TVT-Secur making it unreasonably unsafe and</p> <p>19 unreasonably ineffective were being experienced not</p> <p>20 just in Australia and New Zealand but around the</p> <p>21 world.</p> <p>22 Q. And what else -- is there anything else</p> <p>23 significant from page 10?</p> <p>24 A. It -- this PowerPoint also shows that</p>

16 (Pages 410 to 413)

Bruce Alan Rosenzweig, M.D.

Page 414	Page 416
<p>1 the defects in the Instructions for Use as</p> <p>2 highlighted by "what surgeons said they were doing</p> <p>3 and what we observed them doing were not the same</p> <p>4 things," showing that the Instructions for Use was</p> <p>5 defective.</p> <p>6 Q. Okay. And what's the next slide?</p> <p>7 A. "Additional concerns with 'revised'</p> <p>8 training."</p> <p>9 Q. And what about -- what's the slide</p> <p>10 number?</p> <p>11 A. 13.</p> <p>12 Q. And what about slide 13 is significant</p> <p>13 to your opinions?</p> <p>14 A. That even an analysis of what would be</p> <p>15 the root cause for the deficiencies in training and</p> <p>16 the design characteristics that made it</p> <p>17 unreasonably unsafe and the Instructions for Use</p> <p>18 were not leading to improvements in the safety and</p> <p>19 efficacy of the device.</p> <p>20 Q. Okay. And what else is significant</p> <p>21 about this document?</p> <p>22 MR. SNELL: Object; leading.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. If any.</p>	<p>1 50%.</p> <p>2 Q. So, even after Dr. Lucente retrained</p> <p>3 using his modified technique Australian doctors,</p> <p>4 this document on page 16, it says, "Revised Lucente</p> <p>5 training still yields greater than 50% success</p> <p>6 rate"?</p> <p>7 MR. SNELL: Object and leading.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Is that correct?</p> <p>10 A. Correct.</p> <p>11 Q. And it says, "Australian experiences</p> <p>12 show 'revised' training still can be improved."</p> <p>13 Did I read that correctly?</p> <p>14 MR. SNELL: Object and leading.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Correct.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. What else in this exhibit supports -- is</p> <p>19 relevant to your opinions?</p> <p>20 A. Page 26. It is discussing medical</p> <p>21 literature that was presented in an abstract form</p> <p>22 at an international congress of urogynecologists,</p> <p>23 and it highlights data from 5 to 20 weeks of</p> <p>24 follow-up and that the range of improvement in</p>
Page 415	Page 417
<p>1 A. That surgeons in Australia were</p> <p>2 receiving revised training from Dr. Lucente, that</p> <p>3 Dr. Lucente is a Key Opinion Leader and one of the</p> <p>4 original surgeons in the First Human Use Study.</p> <p>5 Q. Okay. Are you finished with slide --</p> <p>6 with that slide?</p> <p>7 A. Yes.</p> <p>8 Q. All right. Take us to the -- walk us</p> <p>9 through it, Doctor.</p> <p>10 MR. SNELL: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. The next slide is page 16.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And what from page -- what, if anything,</p> <p>15 from page 16 supports your opinions in this case?</p> <p>16 A. This supports my opinions that the</p> <p>17 training was inadequate, the Instructions for Use</p> <p>18 were defective and that the design characteristics</p> <p>19 of the TVT-Secur made it unreasonably unsafe and</p> <p>20 unreasonably ineffective.</p> <p>21 Even with revised training, even with</p> <p>22 revised training from an experienced surgeon, one</p> <p>23 of the first users of the TVT-Secur device,</p> <p>24 Dr. Lucente, failed to yield a success rate over</p>	<p>1 symptoms was from 12 to 26%, which supports my</p> <p>2 opinions that there are characteristics of the</p> <p>3 device that make it unreasonably ineffective to</p> <p>4 treat stress urinary incontinence.</p> <p>5 Q. And actually on page 26 --</p> <p>6 MR. SNELL: Move to strike. Misstates the</p> <p>7 evidence.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. 26 -- I think you read it wrong. It</p> <p>10 says, "Four abstracts with improved rate range from</p> <p>11 12 to 86%." You said 26.</p> <p>12 A. I'm sorry.</p> <p>13 Q. Okay. And let me ask you this question,</p> <p>14 Doctor: It says, "Five abstracts with objective</p> <p>15 cure rate range from 69 to 88%."</p> <p>16 Did I read that correctly?</p> <p>17 A. Correct.</p> <p>18 Q. Is a cure rate using an objective test</p> <p>19 of 69 to 88%, does that demonstrate an efficacious</p> <p>20 product?</p> <p>21 A. Not with follow-up of only 5 to 20</p> <p>22 weeks.</p> <p>23 Q. And what else in this slide deck do you</p> <p>24 want to discuss?</p>

17 (Pages 414 to 417)

Bruce Alan Rosenzweig, M.D.

Page 418	Page 420
<p>1 A. The slide 27.</p> <p>2 Q. And what about slide 27 is significant</p> <p>3 to your opinions?</p> <p>4 A. Well, this supports my opinion that the</p> <p>5 design/development of the TVT-Secur device was</p> <p>6 inadequate; that the device was rushed to market,</p> <p>7 without identifying the design characteristics of</p> <p>8 the device that made it unreasonably unsafe or</p> <p>9 unreasonably ineffective; and that they are</p> <p>10 reinventing the procedure.</p> <p>11 This is in 2008, approximately two years</p> <p>12 after the launch of the product. This should have</p> <p>13 been done during the design and development phase</p> <p>14 of the product, not after it's been placed in</p> <p>15 humans for two years.</p> <p>16 Q. Doctor, is it appropriate for companies</p> <p>17 like Ethicon and Johnson & Johnson to treat</p> <p>18 customers, patients as guinea pigs?</p> <p>19 MR. SNELL: Objection and leading.</p> <p>20 BY THE WITNESS:</p> <p>21 A. No, it is not.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Is it ethical for companies like Ethicon</p> <p>24 and Johnson & Johnson to release products without</p>	<p>1 BY THE WITNESS:</p> <p>2 A. No, it is not.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Is there anything else from Slide No. 27</p> <p>5 that is significant to your opinions?</p> <p>6 A. Yes.</p> <p>7 Q. What is that?</p> <p>8 A. Page 32.</p> <p>9 Q. What, if anything, from page 32 is</p> <p>10 significant to your opinions?</p> <p>11 A. This supports my opinions that the</p> <p>12 design/development of the TVT-Secur device was</p> <p>13 inadequate and there was -- it also supports my</p> <p>14 opinions that there was no -- was insufficient</p> <p>15 clinical data in the use of the device in humans</p> <p>16 prior to launch.</p> <p>17 Q. And on slide 32, do you see where it</p> <p>18 says "Lessons Learned"?</p> <p>19 A. Correct.</p> <p>20 Q. What about slide 32 specifically is</p> <p>21 relevant to your opinion?</p> <p>22 MR. SNELL: Objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Well, this is two years after the launch</p>
Page 419	Page 421
<p>1 first adequately testing those products?</p> <p>2 MR. SNELL: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No, it is not.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Is it ethical for companies like Ethicon</p> <p>7 and Johnson & Johnson to treat customers or</p> <p>8 patients like test subjects?</p> <p>9 MR. SNELL: Objection and leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. No, it is not.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Is it appropriate for companies like</p> <p>14 Ethicon and Johnson & Johnson to treat women like</p> <p>15 test subjects?</p> <p>16 MR. SNELL: Objection and leading.</p> <p>17 BY THE WITNESS:</p> <p>18 A. No, it is not.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Is it appropriate for companies like</p> <p>21 Ethicon and Johnson & Johnson to release products</p> <p>22 into the market without providing or first</p> <p>23 conducting adequate studies?</p> <p>24 MR. SNELL: Objection and leading.</p>	<p>1 of the device, and the lesson that was learned was</p> <p>2 not carrying out the First Human Use Trial and</p> <p>3 launching a product at the same time.</p> <p>4 The learning curve from First Human Use</p> <p>5 Trial should be gathered, digested and the device</p> <p>6 and training adjusted accordingly before launch.</p> <p>7 That supports my opinion that the design and</p> <p>8 development was inadequate to identify the</p> <p>9 characteristics of the device that made it</p> <p>10 unreasonably unsafe and unreasonably ineffective;</p> <p>11 that this information should have been gathered.</p> <p>12 There was insufficient testing in humans</p> <p>13 prior to launch of the product; that this</p> <p>14 information should have been gathered and design</p> <p>15 characteristics that made it unreasonably unsafe or</p> <p>16 unreasonably ineffective should have been found</p> <p>17 prior to launch and either the device or the</p> <p>18 Instructions for Use or the training corrected, if</p> <p>19 possible, or the device not launched to the market.</p> <p>20 Q. Do you agree with the statement by</p> <p>21 Ethicon on slide 32 that "The learnings from a</p> <p>22 First Human Use Trial should be gathered, digested</p> <p>23 and the device/training adjusted accordingly before</p> <p>24 launch"?</p>

18 (Pages 418 to 421)

Bruce Alan Rosenzweig, M.D.

Page 422	Page 424
<p>1 MR. SNELL: Objection and leading.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Are those your words or the words from</p> <p>6 somebody at Ethicon?</p> <p>7 A. Those are the words from Ethicon.</p> <p>8 Q. And are we -- is this serious?</p> <p>9 A. Yes.</p> <p>10 MR. SNELL: Objection.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Ethicon puts a product on the market</p> <p>13 without conducting appropriate tests and then</p> <p>14 writes a slide about lessons it had to learn from</p> <p>15 that conduct?</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes.</p> <p>19 MR. SNELL: And leading.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. This seems rather obvious to me.</p> <p>22 MR. SNELL: Leading.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. I mean --</p>	<p>1 A. That is inappropriate.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Despite claiming in this PowerPoint</p> <p>4 slide to have learned a lesson, what did Ethicon do</p> <p>5 about the lesson it learned?</p> <p>6 MR. SNELL: Objection; leading.</p> <p>7 BY THE WITNESS:</p> <p>8 A. They continued to sell the product in</p> <p>9 the United States.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Was that appropriate?</p> <p>12 MR. SNELL: Objection.</p> <p>13 BY THE WITNESS:</p> <p>14 A. No.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Is there anything else from</p> <p>17 Exhibit P706?</p> <p>18 A. No.</p> <p>19 Q. What's the next document you want to</p> <p>20 discuss with the jury?</p> <p>21 A. P1102.</p> <p>22 Q. And can you -- can you identify what</p> <p>23 P1102 is?</p> <p>24 A. Yes. It is an e-mail string from</p>
Page 423	Page 425
<p>1 MR. SNELL: Objection as well, relevancy as to</p> <p>2 Plaintiffs' counsel.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Is it appropriate for a company like</p> <p>5 Johnson & Johnson to learn a lesson in 2007 for the</p> <p>6 first time apparently that it's inappropriate to</p> <p>7 put a product on the market without first testing</p> <p>8 it?</p> <p>9 MR. SNELL: Objection and leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. That is not appropriate.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Do you have an opinion with respect to</p> <p>14 the conduct of Ethicon in releasing the TVT-Secur</p> <p>15 product without receiving the final results from</p> <p>16 the First Human Use Trial?</p> <p>17 A. Yes.</p> <p>18 MR. SNELL: Objection and leading. Go ahead.</p> <p>19 BY THE WITNESS:</p> <p>20 A. I have an opinion.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. What's that opinion?</p> <p>23 MR. SNELL: Same objection.</p> <p>24 BY THE WITNESS:</p>	<p>1 Dr. Neuman, who is a surgeon in Israel, a Key</p> <p>2 Opinion Leader, someone who has experience with the</p> <p>3 TVT-Secur device.</p> <p>4 Q. And what's the date of this e-mail</p> <p>5 string?</p> <p>6 A. February 20, 2008.</p> <p>7 Q. And how long had the TVT-Secur been on</p> <p>8 the market by this point?</p> <p>9 A. Approximately a year and a half.</p> <p>10 Q. And what is significant, if anything, in</p> <p>11 Exhibit P1102?</p> <p>12 MR. SNELL: Objection.</p> <p>13 BY THE WITNESS:</p> <p>14 A. This document supports my opinions about</p> <p>15 the design characteristics of the TVT-Secur device</p> <p>16 that make it unreasonably unsafe.</p> <p>17 This is describing the stiffness of the</p> <p>18 mesh that due to the laser cutting is responsible</p> <p>19 for pain and the mesh eroding through the vaginal</p> <p>20 tissues; that the edges of the device are too</p> <p>21 sharp; and those design characteristics are leading</p> <p>22 to the harm in women, which is pain and mesh</p> <p>23 erosion.</p> <p>24 BY MR. THORNBURGH:</p>

19 (Pages 422 to 425)

Bruce Alan Rosenzweig, M.D.

Page 426	Page 428
<p>1 Q. Who is Dr. Neuman?</p> <p>2 A. Dr. Neuman is a pelvic surgeon in</p> <p>3 Israel, a Key Opinion Leader, a consultant for</p> <p>4 Ethicon.</p> <p>5 Q. And what does Dr. Neuman state to</p> <p>6 Dr. Robinson, Dr. Gadot, Mr. -- I'm sorry --</p> <p>7 Mr. Gadot, Mr. Smith and Mr. Ciarrocca?</p> <p>8 MR. SNELL: Objection and leading.</p> <p>9 BY THE WITNESS:</p> <p>10 A. He is describing "Due to the increase in</p> <p>11 late failures and protrusion rate, I held now a</p> <p>12 two-armed comparison of TVT-Secur versus TVT-O.</p> <p>13 Actually, there were more postoperative</p> <p>14 obstruction, vaginal pain and tape protrusion with</p> <p>15 the TVT-Secur. Most of the vaginal pain and</p> <p>16 lateral protrusion is caused by the increased tape</p> <p>17 stiffness - my feeling it is due to laser cutting.</p> <p>18 The edges should be thinner and rounder. There are</p> <p>19 too many undesired tape removals are reported."</p> <p>20 Q. And does this document support your</p> <p>21 opinions?</p> <p>22 A. Yes, about the design characteristics of</p> <p>23 the device that make it unreasonably unsafe.</p> <p>24 Q. Doctor, what type of study is Dr. Neuman</p>	<p>1 A. That the vaginal pain and the lateral</p> <p>2 protrusions are caused by the increased stiffness</p> <p>3 of the mesh which is due to laser cutting, which</p> <p>4 supports my opinion of the design defect of mesh,</p> <p>5 short, stiff mesh increases the harm of pain and</p> <p>6 mesh exposure into the -- or erosion into the</p> <p>7 vagina or other pelvic structures.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Dr. Neuman goes on to say, "I do believe</p> <p>10 that as soon as those points will be addressed, the</p> <p>11 TVT-Secur may be able to be as efficient and user</p> <p>12 friendly as the TVT and TVT-O."</p> <p>13 Did I read that correctly?</p> <p>14 A. Yes.</p> <p>15 MR. SNELL: Objection and leading.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Did Ethicon ever address those points</p> <p>18 that were outlined by Dr. Neuman?</p> <p>19 MR. SNELL: Objection; leading.</p> <p>20 BY THE WITNESS:</p> <p>21 A. No.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Do you have an opinion whether or not</p> <p>24 Ethicon should have addressed those points?</p>
Page 427	Page 429
<p>1 discussing in this e-mail?</p> <p>2 A. A prospective comparative trial.</p> <p>3 Q. Is that a randomized controlled trial,</p> <p>4 do you know?</p> <p>5 A. It is not specifically discussed as a</p> <p>6 randomized controlled trial.</p> <p>7 Q. Did Ethicon, before they launched the</p> <p>8 TVT-Secur on the market, perform a prospective</p> <p>9 comparative trial?</p> <p>10 A. Their initial Human Use Trial was a</p> <p>11 prospective single-arm trial of just the TVT-Secur.</p> <p>12 Q. And Dr. Neuman is identifying -- do you</p> <p>13 see -- strike that.</p> <p>14 Do you see on No. 5 of Dr. Neuman's</p> <p>15 list?</p> <p>16 A. Yes.</p> <p>17 MR. SNELL: Object; leading.</p> <p>18 MR. THORNBURGH: Can you go ahead and blow up</p> <p>19 No. 5 for us.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. What does Dr. Neuman state to Ethicon</p> <p>22 employees in this section?</p> <p>23 MR. SNELL: Object; leading.</p> <p>24 BY THE WITNESS:</p>	<p>1 MR. SNELL: Same objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. What's that opinion?</p> <p>6 A. They should have addressed those design</p> <p>7 characteristics that make the device unreasonably</p> <p>8 unsafe.</p> <p>9 Q. Why?</p> <p>10 A. Because those are design characteristics</p> <p>11 that lead to harm in women.</p> <p>12 MR. THORNBURGH: Let's go ahead and take a</p> <p>13 break.</p> <p>14 THE VIDEOGRAPHER: Okay. The time is 10:26</p> <p>15 a.m. This is the end of Tape 1 and we are going</p> <p>16 off the video record.</p> <p>17 (WHEREUPON, a recess was had</p> <p>18 from 10:26 to 10:43 a.m.)</p> <p>19 THE VIDEOGRAPHER: The time is 10:43 a.m.</p> <p>20 This is the beginning of Tape 2 and we are back on</p> <p>21 the video record.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Now, Doctor, before we took a break we</p> <p>24 were looking at Exhibit P1102 and that was an</p>

Bruce Alan Rosenzweig, M.D.

Page 430	Page 432
<p>1 e-mail, as you recall, from Dr. Neuman to David 2 Robinson, Harel Gadot, Dan Smith and Scott 3 Ciarrocca, correct? 4 A. Correct. 5 Q. Okay. Just want to walk through this 6 document with you really quick. 7 Do you see where it says, "Dear all, 8 Attached is my TVT-S complication summary"? 9 A. Yes. 10 Q. And if you look at No. 1, Dr. Neuman 11 writes, "Own surgical experience." 12 Do you see that? 13 MR. SNELL: Object; leading. 14 BY THE WITNESS: 15 A. Yes. 16 BY MR. THORNBURGH: 17 Q. And you'll see that he lists the number 18 of patients he's implanted with different medical 19 devices for the treatment of either stress urinary 20 incontinence or prolapse? 21 MR. SNELL: Object; leading. 22 BY MR. THORNBURGH: 23 Q. Is that correct? 24 A. Correct.</p>	<p>1 Q. And can you explain to the ladies and 2 gentlemen of the jury your understanding of 3 protrusion rate? 4 A. The -- that is the rate with which the 5 mesh erodes through the vaginal tissue. 6 Q. Turn the page to Bates number ending in 7 3122. 8 What does Dr. Neuman write with respect 9 to No. 3? 10 MR. SNELL: Object. 11 BY THE WITNESS: 12 A. "There was no superiority for the 13 TVT-Secur over TVT-O in terms of safety, ease, 14 success, complications or pain. Actually, there 15 were more postoperative obstruction, vaginal pain 16 and tape protrusion with the TVT-S." 17 BY MR. THORNBURGH: 18 Q. And what's the significance, if any, of 19 that statement? 20 A. It supports my opinions about the design 21 characteristics of the TVT-Secur that are 22 unreasonably unsafe. 23 Q. And if you look at No. 4, what does 24 Dr. Neuman write?</p>
Page 431	Page 433
<p>1 Q. And do you see -- how many -- how many 2 patients at this point in 2008 had Dr. Neuman 3 implanted with the TVT-Secur? 4 A. 447. 5 Q. And how many does Dr. -- how many 6 patients does Dr. Neuman indicate he was part of 7 the training for these implantation of the 8 TVT-Secur device? 9 A. 229. 10 Q. Would you consider Dr. Neuman to be an 11 experienced surgeon? 12 A. Yes. 13 Q. And do you see No. 2? What does 14 Dr. Neuman write? 15 A. "Due to slightly increased late failure 16 rate and protrusion rate I held now a two-armed 17 comparison of TVT-Secur versus TVT-O (Flam 18 method)." 19 Q. Okay. And just so we all understand in 20 lay terms. What is your understanding of "late 21 failure"? 22 A. That after the recovery period and more 23 likely than not after one year, that the device 24 failed.</p>	<p>1 MR. SNELL: Object. 2 BY THE WITNESS: 3 A. "Having some experience with these three 4 different modalities of minimally invasive 5 anti-incontinence operations, it's become obvious 6 that the TVT and TVT-O were initiated by surgeons 7 while the TVT-S was designed purely by engineers. 8 The TVT-S is very smart, regarding mesh production 9 and even more with insertion mechanism. At the 10 same time, the TVT-O" -- "the TVT and the TVT-O 11 were 'anatomical' and very 'surgical' or I may say 12 very 'surgeon friendly.'" (As read.) 13 Q. And do you have an understanding as 14 to -- as to what Dr. Neuman -- what's your 15 interpretation of what Dr. Neuman is writing here 16 with respect to the TVT-Secur being designed purely 17 by engineers? 18 MR. SNELL: Objection. 19 BY THE WITNESS: 20 A. That being designed by an engineer, an 21 engineer would not understand the -- have the 22 training and experience of a medical doctor. 23 BY MR. THORNBURGH: 24 Q. And who designed the TVT-Secur?</p>

21 (Pages 430 to 433)

Bruce Alan Rosenzweig, M.D.

Page 434	Page 436
<p>1 MR. SNELL: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Dan Smith.</p> <p>4 BY THE WITNESS:</p> <p>5 Q. And what was Dan Smith's -- can you</p> <p>6 remind -- strike that.</p> <p>7 Can you remind us, what was Dan Smith's</p> <p>8 background?</p> <p>9 MR. SNELL: Object.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Dan Smith is an engineer.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And what does Dr. Neuman write next?</p> <p>14 MR. SNELL: Object; leading.</p> <p>15 BY THE WITNESS:</p> <p>16 A. "All the TVT-Secur weak points - as I</p> <p>17 see them: Most of the vaginal pain and lateral</p> <p>18 protrusion is caused by the increased tape</p> <p>19 stiffness - my feeling is due to the laser</p> <p>20 cutting."</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Let's stop right there for a second.</p> <p>23 What's the significance, if any, with</p> <p>24 that statement by Dr. Neuman?</p>	<p>1 more" -- excuse me.</p> <p>2 "The TVT-Secur is attached in general to</p> <p>3 more operative bleeding than the TVT and the TVT-O</p> <p>4 and requires more force for introduction. The</p> <p>5 edges should be thinner and rounder. This will</p> <p>6 reduce the vaginal injury ('button halls')," which</p> <p>7 is a typographical error meaning button holes, "as</p> <p>8 well. The detachment is not smooth enough, too</p> <p>9 many undesired tape removals are reported."</p> <p>10 Q. Okay. What is your understanding as or</p> <p>11 interpretation of this statement by Dr. Neuman?</p> <p>12 A. This statement supports my opinions of</p> <p>13 the design characteristic of the TVT-Secur device.</p> <p>14 The sharp introducer edges are too sharp, which</p> <p>15 leads to the harm of injury to the vaginal wall,</p> <p>16 which can lead to bleeding and pain and erosion of</p> <p>17 the mesh in women.</p> <p>18 Q. Now, what are -- what is your opinion --</p> <p>19 do you have an opinion with respect to the</p> <p>20 different -- strike that.</p> <p>21 What is your opinion with respect to the</p> <p>22 Secur device and any defects that you've listed?</p> <p>23 What are those defects, if you could just outline</p> <p>24 them?</p>
Page 435	Page 437
<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. That demonstrates the design</p> <p>4 characteristic of the short, stiff, rigid mesh that</p> <p>5 it -- that is unreasonably unsafe and leads to the</p> <p>6 harm of vaginal pain and erosion of the mesh</p> <p>7 through the vagina.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And does that statement by Dr. Neuman</p> <p>10 provide any support for your opinions?</p> <p>11 A. Yes.</p> <p>12 Q. What opinion?</p> <p>13 A. The laser-cut, stiff, rigid, short mesh</p> <p>14 is a design characteristic of the TVT-Secur that is</p> <p>15 unreasonably unsafe.</p> <p>16 Q. What do you mean by "unreasonably</p> <p>17 unsafe"?</p> <p>18 A. It leads to the harm of vaginal pain and</p> <p>19 erosion of the mesh into the vagina.</p> <p>20 Q. And what does Dr. Neuman next write?</p> <p>21 A. "The TVT" --</p> <p>22 MR. SNELL: Objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. -- "Secur is attached in general to</p>	<p>1 MR. SNELL: Objection.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Lay them out for us or tell us what they</p> <p>4 are real quick.</p> <p>5 A. That the device was not studied prior to</p> <p>6 release; that the training was not effective; that</p> <p>7 the Instructions for Use is defective; that the</p> <p>8 characteristics of the device that make it</p> <p>9 unreasonably unsafe and unreasonably ineffective</p> <p>10 include the sharp arrow tip introducer is too sharp</p> <p>11 and drags across vaginal tissue.</p> <p>12 The fleece ends do not hold the mesh in</p> <p>13 place to support the urethra.</p> <p>14 The tape being short and laser-cut is</p> <p>15 too short and stiff, which leads to harm of the</p> <p>16 vagina, the urethra, which leads to the harms of</p> <p>17 pain, erosion and pain with intercourse, just to</p> <p>18 name a few.</p> <p>19 Q. And did you create a PowerPoint slide</p> <p>20 that summarizes those design characteristics?</p> <p>21 A. Yes.</p> <p>22 Q. And your opinions with respect to those</p> <p>23 design characteristics?</p> <p>24 A. Yes.</p>

22 (Pages 434 to 437)

Bruce Alan Rosenzweig, M.D.

Page 438	Page 440
<p>1 MR. THORNBURGH: I'm going to mark as</p> <p>2 Exhibit No. 6, and this would be I think -- we have</p> <p>3 been calling them BR-Secur 6.</p> <p>4 (WHEREUPON, a certain document was</p> <p>5 marked as BR-Secur Exhibit No. 6:</p> <p>6 "Design Defects" slide.)</p> <p>7 MR. SNELL: It's not the same thing you're</p> <p>8 looking at.</p> <p>9 MR. THORNBURGH: It's the same one I marked.</p> <p>10 MR. SNELL: Okay.</p> <p>11 MR. THORNBURGH: If you can go ahead and pull</p> <p>12 that up for us, Tom.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Does this PowerPoint slide that you</p> <p>15 created, will it help the jury understand what your</p> <p>16 opinions are with respect to the defects in the</p> <p>17 design characteristics?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Correct.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. And can you identify those design</p> <p>23 defects?</p> <p>24 A. Yes. The stiff, rigid and dense mesh</p>	<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. He states, "Let's discuss before taking</p> <p>4 action."</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Did Ethicon ever take any action?</p> <p>7 MR. SNELL: Objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. No.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Do you have an opinion about whether or</p> <p>12 not Ethicon should have taken action?</p> <p>13 MR. SNELL: Same.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yes.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Do you have an opinion as to what action</p> <p>18 Ethicon should have taken?</p> <p>19 MR. SNELL: Same.</p> <p>20 BY THE WITNESS:</p> <p>21 A. The action that should have been taken</p> <p>22 was to either resolve the defective design</p> <p>23 characteristics of the device to make it reasonably</p> <p>24 safe and reasonably effective or discontinue the</p>
Page 439	Page 441
<p>1 increases the risk for chronic foreign body</p> <p>2 reaction, chronic inflammatory reaction, excessive</p> <p>3 scarring, fibrotic bridging, scar-plating of the</p> <p>4 mesh, encapsulation of the mesh, mesh shrinkage and</p> <p>5 contraction; the failure to adequately study the</p> <p>6 TVT-Secur system; the defective implant</p> <p>7 procedure/technique and absorbable fleece tips; the</p> <p>8 defective implanter mechanisms and instruments</p> <p>9 including the sharp arrow tip introducer.</p> <p>10 Q. And are at least some of your opinions</p> <p>11 that you've identified in Exhibit 6 consistent with</p> <p>12 the concerns that are being raised by Dr. Neuman in</p> <p>13 2008?</p> <p>14 MR. SNELL: Object.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Now, if we go back to the Neuman e-mail,</p> <p>19 Exhibit P1102, does -- do you see the top of the</p> <p>20 e-mail, the top of the exhibit?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And what does Andrew Beveridge</p> <p>23 write in response to the concerns that were</p> <p>24 outlined by Dr. Neuman?</p>	<p>1 product from the market.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And I'm going to ask this similarly but</p> <p>4 in a different way.</p> <p>5 Do you have an opinion about whether or</p> <p>6 not Ethicon could have taken action?</p> <p>7 MR. SNELL: Objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Yes.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And what action in your opinion could</p> <p>12 Ethicon have taken?</p> <p>13 MR. SNELL: Objection.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Ethicon could have identified the design</p> <p>16 characteristics that make the TVT-Secur device</p> <p>17 unreasonably unsafe or unreasonably ineffective and</p> <p>18 corrected those or, if they could not, remove the</p> <p>19 product from the market.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Okay. What's the next exhibit you want</p> <p>22 to discuss with the jury?</p> <p>23 A. P0292.</p> <p>24 Q. Can you identify Exhibit P290 (sic) to</p>

23 (Pages 438 to 441)

Bruce Alan Rosenzweig, M.D.

Page 442	Page 444
<p>1 the jury?</p> <p>2 A. Yes, it is an e-mail from February of</p> <p>3 2008 from Medical Director Dr. David Robinson to</p> <p>4 other key Ethicon employees worldwide.</p> <p>5 MR. THORNBURGH: One second.</p> <p>6 MR. SNELL: While he is looking, can you tell</p> <p>7 me the P number again, Doctor.</p> <p>8 THE WITNESS: Yes, it is P0292.</p> <p>9 MR. SNELL: Thank you very much.</p> <p>10 MR. THORNBURGH: Can we go off the record real</p> <p>11 quick.</p> <p>12 THE VIDEOGRAPHER: The time is 10:58 a.m. and</p> <p>13 we're going off the video record.</p> <p>14 (WHEREUPON, a recess was had</p> <p>15 from 10:58 to 11:03 a.m.)</p> <p>16 THE VIDEOGRAPHER: The time is 11:03 a.m. and</p> <p>17 we're back on the video record.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Sorry about that, Doctor.</p> <p>20 You just identified Exhibit 292 as the</p> <p>21 next exhibit that you wanted to speak about, is</p> <p>22 that correct?</p> <p>23 A. Correct.</p> <p>24 Q. Okay. And can you identify this exhibit</p>	<p>1 his colleagues?</p> <p>2 A. "Clinically, there may be an impact of</p> <p>3 increased rigidity with any given mesh as it may</p> <p>4 increase vaginal stiffness post-op with the</p> <p>5 potential of impaired sexual function.</p> <p>6 Unfortunately, to quantitate what represents a</p> <p>7 meaningful difference in rigidity may be impossible</p> <p>8 to define. Suffice it to say, however, all meshes</p> <p>9 we are working on for the future will be less rigid</p> <p>10 than our current Gynemesh PS."</p> <p>11 Q. Okay. And what is Gynemesh PS?</p> <p>12 A. Gynemesh PS is a larger pore,</p> <p>13 lighter-weight mesh compared to the Prolene mesh in</p> <p>14 the TVT-Secur.</p> <p>15 Q. So, was Gynemesh more rigid or less</p> <p>16 rigid than the mesh used in the TVT-Secur?</p> <p>17 A. Gynemesh PS is less rigid and less stiff</p> <p>18 than the Prolene mesh in TVT-Secur.</p> <p>19 Q. What's the next exhibit you want to</p> <p>20 speak about, Doctor?</p> <p>21 A. P0686.</p> <p>22 Q. And can you identify P0686 for the</p> <p>23 ladies and gentlemen of the jury?</p> <p>24 A. Yes, it is an e-mail string between key</p>
Page 443	Page 445
<p>1 for the ladies and gentlemen of the jury.</p> <p>2 A. Yes, this is an e-mail string from</p> <p>3 February 29, 2008 from Dr. David Robinson to other</p> <p>4 key Ethicon employees around the world.</p> <p>5 Q. And what opinions does Exhibit 292</p> <p>6 support, if any?</p> <p>7 A. This supports my opinion that the short,</p> <p>8 stiff, laser-cut mesh in the TVT-Secur, the design</p> <p>9 characteristics that make it unreasonably unsafe,</p> <p>10 lead to the harm of pain with intercourse.</p> <p>11 Q. And how does this exhibit support that</p> <p>12 opinion?</p> <p>13 A. It supports that opinion because this is</p> <p>14 a statement from a Medical Director of Ethicon,</p> <p>15 Dr. David Robinson, regarding increased stiffness</p> <p>16 and rigidity of mesh is responsible for impaired</p> <p>17 sexual function.</p> <p>18 Q. Okay. And if we pull up Exhibit 292,</p> <p>19 what page supports that opinion?</p> <p>20 A. 8896.</p> <p>21 MR. THORNBURGH: Go ahead and pull up 8896 and</p> <p>22 go ahead and blow up the middle.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. What does Dr. David Robinson write to</p>	<p>1 Ethicon employees, including Harel Gadot, marketing</p> <p>2 director worldwide, from March 3, 2008.</p> <p>3 Q. And what opinion, if any, does P0686</p> <p>4 support?</p> <p>5 A. That the TVT-Secur device is</p> <p>6 effective -- excuse me -- is defective. It has</p> <p>7 design characteristics that make it unreasonably</p> <p>8 ineffective in treating stress urinary</p> <p>9 incontinence.</p> <p>10 Q. How does Exhibit P0686 support that</p> <p>11 opinion?</p> <p>12 A. This document describes that Ethicon</p> <p>13 must have an efficient mini-sling, which would mean</p> <p>14 that their current mini-sling, which is the</p> <p>15 TVT-Secur, is inefficient, therefore it has design</p> <p>16 characteristics that make it unreasonably</p> <p>17 ineffective to treat stress urinary incontinence.</p> <p>18 Q. Now, you identified the date as being</p> <p>19 March 3 of 2008, is that correct?</p> <p>20 A. Correct.</p> <p>21 Q. Was the TVT-Secur already on the market</p> <p>22 at this point?</p> <p>23 MR. SNELL: Objection.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 446	Page 448
<p>1 A. Yes.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Okay. And was -- did Ethicon have any</p> <p>4 other mini-sling on the market on March 3 of 2008?</p> <p>5 A. No.</p> <p>6 Q. Okay. Now, can you direct us to the</p> <p>7 portion of this exhibit that supports your opinion?</p> <p>8 A. Yes. It's ETH.MESH number ending in</p> <p>9 9976.</p> <p>10 Q. And how does the ETH.MESH number or that</p> <p>11 page support your opinion?</p> <p>12 A. This document states, "If we want to</p> <p>13 grow (and protect) our," in quotations, "cash cow"</p> <p>14 market share/potential, we must have an efficient</p> <p>15 mini-sling. If we do not do so, someone else</p> <p>16 will."</p> <p>17 Q. Did Ethicon ever disclose to doctors --</p> <p>18 strike that.</p> <p>19 Based on your review of Ethicon's</p> <p>20 internal documents, did they ever disclose to</p> <p>21 physicians who were implanting patients with the</p> <p>22 TVT-Secur device that they were looking for a more</p> <p>23 efficient mini-sling?</p> <p>24 A. No.</p>	<p>1 Q. What's the next exhibit you want to</p> <p>2 discuss?</p> <p>3 A. P0946.</p> <p>4 Q. What is P049 -- sorry -- 0946?</p> <p>5 A. It is an e-mail string from -- between</p> <p>6 key Ethicon employees from April 16, 2008.</p> <p>7 Q. How does Exhibit P0 -- sorry. Strike</p> <p>8 that.</p> <p>9 MR. SNELL: Can I get a copy?</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. What opinion does Exhibit P0946 support?</p> <p>12 A. It supports my opinion that there are</p> <p>13 design characteristics that make the TVT-Secur</p> <p>14 device unreasonably unsafe and unreasonably</p> <p>15 ineffective and that there was a failure to</p> <p>16 adequately study the device before putting the</p> <p>17 device on the market.</p> <p>18 Q. How does it support that opinion,</p> <p>19 Doctor?</p> <p>20 A. This is an e-mail that is discussing</p> <p>21 registry data that was collected that was from a</p> <p>22 project called TVT-WORLD. TVT-WORLD was a registry</p> <p>23 that was collecting data on all of the TVT</p> <p>24 products.</p>
Page 447	Page 449
<p>1 Q. Is it appropriate for companies like</p> <p>2 Johnson & Johnson or Ethicon to continue to sell</p> <p>3 inefficient products or ineffective products in</p> <p>4 order to protect their cash cow or to protect their</p> <p>5 market share until they developed a more effective</p> <p>6 product?</p> <p>7 MR. SNELL: Objection and MIL, cash cow.</p> <p>8 BY THE WITNESS:</p> <p>9 A. No.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Why not?</p> <p>12 MR. SNELL: Same.</p> <p>13 BY THE WITNESS:</p> <p>14 A. A device that has design characteristics</p> <p>15 that make it unreasonably ineffective to treat</p> <p>16 stress urinary incontinence must -- those</p> <p>17 characteristics must be understood and either</p> <p>18 corrected to make it an efficient treatment for</p> <p>19 stress urinary incontinence or the product should</p> <p>20 be removed from the market.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Any other -- anything else significant</p> <p>23 from this exhibit?</p> <p>24 A. No.</p>	<p>1 This e-mail is discussing spinning the</p> <p>2 data from the TVT-WORLD and if that is done, it</p> <p>3 would lose its objectivity.</p> <p>4 Q. Doctor, what does "spin data" mean to</p> <p>5 you?</p> <p>6 A. To manipulate the data to create more</p> <p>7 favorable data.</p> <p>8 Q. Is it appropriate for companies like</p> <p>9 Ethicon and Johnson & Johnson to spin data from</p> <p>10 their studies?</p> <p>11 MR. SNELL: Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. No.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Why not?</p> <p>16 MR. SNELL: Same.</p> <p>17 BY THE WITNESS:</p> <p>18 A. It is important to report accurate data,</p> <p>19 whether it is favorable data or unfavorable data,</p> <p>20 so that doctors have a clear understanding about</p> <p>21 what the safety and efficacy is of a product in</p> <p>22 order to be able to determine whether or not that</p> <p>23 product is acceptable and appropriate for use in</p> <p>24 the treatment of stress urinary incontinence for</p>

25 (Pages 446 to 449)

Bruce Alan Rosenzweig, M.D.

Page 450	Page 452
<p>1 women.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. What could happen to patients who get</p> <p>4 implanted with a product that's based on or</p> <p>5 supported by data that had been spun or</p> <p>6 manipulated?</p> <p>7 MR. SNELL: Object.</p> <p>8 BY THE WITNESS:</p> <p>9 A. They can be exposed to unreasonable</p> <p>10 hazard.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Doctor, I got to ask you this question.</p> <p>13 Have you ever -- strike that.</p> <p>14 Before you got involved in this</p> <p>15 litigation, did you have any expectation that</p> <p>16 Johnson & Johnson or Ethicon would spin their data</p> <p>17 in order for their data to look better than it</p> <p>18 actually was?</p> <p>19 MR. SNELL: Object.</p> <p>20 BY THE WITNESS:</p> <p>21 A. No.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. I want to turn your attention to Bates</p> <p>24 number ending in 6215. Do you see the e-mail from</p>	<p>1 device companies like Ethicon and Johnson & Johnson</p> <p>2 to behave in an objective and scientifically robust</p> <p>3 manner?</p> <p>4 MR. SNELL: Object.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes, I do have an opinion.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. What's the opinion?</p> <p>9 MR. SNELL: Same.</p> <p>10 BY THE WITNESS:</p> <p>11 A. That they should have behave in an</p> <p>12 objective and scientifically robust manner.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Why is that?</p> <p>15 A. So that --</p> <p>16 MR. SNELL: Same.</p> <p>17 BY THE WITNESS:</p> <p>18 A. The information regarding the risks and</p> <p>19 benefits of the devices that they are producing to</p> <p>20 be permanently implanted in a woman are known so</p> <p>21 that doctors can make a decision about which</p> <p>22 products they use for their patients and that</p> <p>23 patients can make an informed decision about the</p> <p>24 products that they're having permanently implanted</p>
Page 451	Page 453
<p>1 Judi Gauld to David Robinson dated April 16, 2008?</p> <p>2 A. Yes.</p> <p>3 Q. And what does Judi Gauld write to David</p> <p>4 Robinson?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. "I hear your frustration with this</p> <p>8 situation and apologize if I continue to push back</p> <p>9 on this. However, I do feel very strongly about</p> <p>10 this situation, and will continue to push back on</p> <p>11 my own. I am really concerned that the lines</p> <p>12 between commercial and research need to be clear</p> <p>13 cut, and in this company, am continually amazed and</p> <p>14 surprised at our need to push back. I understand</p> <p>15 the need to keep our relationships good with</p> <p>16 marketing, and believe it is possible if we are</p> <p>17 trusted and respected in doing our jobs. We" --</p> <p>18 excuse me. "More importantly for me is that we are</p> <p>19 able to continue to work with the best</p> <p>20 urogynecologists in a research setting and that</p> <p>21 they see us as behaving in an objective and</p> <p>22 scientifically robust manner."</p> <p>23 Q. Is it important -- do you have an</p> <p>24 opinion whether or not it's important for medical</p>	<p>1 in their body.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And if you turn to the first page of</p> <p>4 P0946, do you see there is another response from</p> <p>5 Judi Gauld to David Robinson?</p> <p>6 A. Yes.</p> <p>7 Q. And what does -- what does Judi Gauld</p> <p>8 tell Dr. Robinson in this response?</p> <p>9 MR. SNELL: Object.</p> <p>10 BY THE WITNESS:</p> <p>11 A. "I know what you're saying about HE&R -</p> <p>12 my concern with Dhinagar is his closeness to EU</p> <p>13 marketing and his constant wish to 'spin' data e.g.</p> <p>14 TVT-WORLD interim - and therefore lose objectivity."</p> <p>15 (As read.)</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Have you seen -- have you seen</p> <p>18 Dhinagar's name before?</p> <p>19 A. Yes.</p> <p>20 Q. And where have you seen Dhinagar's name?</p> <p>21 A. On other publications.</p> <p>22 Q. And are you aware whether or not</p> <p>23 Dhinagar was involved in the publication of the</p> <p>24 TVT-WORLD data?</p>

Bruce Alan Rosenzweig, M.D.

Page 454	Page 456
<p>1 A. Yes.</p> <p>2 Q. In what -- in what sense?</p> <p>3 A. As an investigator.</p> <p>4 Q. Do you agree with Dr. Gauld that it is</p> <p>5 inappropriate to spin data?</p> <p>6 MR. SNELL: Object.</p> <p>7 BY THE WITNESS:</p> <p>8 A. First, I don't think Ms. Gauld is a</p> <p>9 physician.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Sorry. Let me ask the question again.</p> <p>12 Do you agree with Ms. Gauld that it is</p> <p>13 inappropriate to spin data?</p> <p>14 MR. SNELL: Objection. Go ahead.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes, I agree with that.</p> <p>17 MR. SNELL: Defense will object to P0946. We</p> <p>18 have been unable to locate it on Dr. Rosenzweig's</p> <p>19 reliance list. So, we will move to strike all</p> <p>20 questioning about this document.</p> <p>21 MR. THORNBURGH: It's on there.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What's the next document you want to</p> <p>24 discuss, Doctor.</p>	<p>1 Does Ethicon often cite to Dr. Nilsson</p> <p>2 as an expert in the field?</p> <p>3 MR. SNELL: Object. Go ahead.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Does -- in your view of Ethicon's</p> <p>8 internal documents, did Ethicon hold Dr. Nilsson</p> <p>9 out as an expert in the field of urogynecology?</p> <p>10 MR. SNELL: Object and leading.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And we've heard about Dr. Nilsson</p> <p>15 yesterday, is that correct?</p> <p>16 A. Correct.</p> <p>17 Q. And just to refresh the jury's</p> <p>18 recollection, what was Dr. Nilsson's involvement</p> <p>19 with the TVT-Secur product, if any?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Dr. Nilsson was one of the participants</p> <p>23 in the First Human Use Study.</p> <p>24 BY MR. THORNBURGH:</p>
Page 455	Page 457
<p>1 A. It is P1128.</p> <p>2 Q. And can you identify for the jury what</p> <p>3 P1128 is?</p> <p>4 A. Yes. It is an interview with Dr. Carl</p> <p>5 Nilsson with Dan Smith and several other key</p> <p>6 Ethicon employees.</p> <p>7 Q. And what opinion --</p> <p>8 MR. SNELL: Can I get a copy.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. What opinion, if any, does Exhibit P1128</p> <p>11 support?</p> <p>12 A. It supports my opinions about the design</p> <p>13 characteristics of the TVT-Secur device that make</p> <p>14 it unreasonably unsafe or unreasonably ineffective.</p> <p>15 Q. How does P1128 support your opinions?</p> <p>16 A. It is an interview with Dr. Carl</p> <p>17 Nilsson, again, one of the original users of the</p> <p>18 TVT Retropubic, a Key Opinion Leader, Ethicon</p> <p>19 consultant, and one of the surgeons that probably</p> <p>20 has the most experience with midurethral slings.</p> <p>21 Q. And did Dr. Nilsson publish data</p> <p>22 concerning the TVT Retropubic device?</p> <p>23 A. Yes.</p> <p>24 Q. And does Dr. Nilsson -- strike that.</p>	<p>1 Q. And what did Dr. -- what types of</p> <p>2 studies, if any, did Dr. Nilsson believe needed to</p> <p>3 be conducted before TVT-Secur was launched?</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Randomized controlled trials.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Okay. Now, if we -- what's the title of</p> <p>9 this document? If you go ahead and look at the</p> <p>10 first page of P1128, top left-hand corner.</p> <p>11 A. "KOL interview: Carl G. Nilsson," dated</p> <p>12 6/18/08.</p> <p>13 Q. July 18 of 2008, is Ethicon still</p> <p>14 marketing and selling the TVT-Secur product?</p> <p>15 MR. SNELL: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Correct.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And what is -- do you see where it says</p> <p>20 "Project Scion"?</p> <p>21 A. Yes.</p> <p>22 Q. Are you familiar with Project Scion?</p> <p>23 A. Somewhat, yes.</p> <p>24 Q. Was Project Scion another device that</p>

Bruce Alan Rosenzweig, M.D.

Page 458	Page 460
<p>1 Ethicon was developing?</p> <p>2 MR. SNELL: Objection; leading.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. I will ask a better question.</p> <p>5 What was Project Scion?</p> <p>6 MR. SNELL: No objection.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Project Scion was another women's health</p> <p>9 product that Ethicon was developing.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And who attended this meeting?</p> <p>12 A. Dr. Nilsson, Dan Smith, Susanne</p> <p>13 Landgrebe, Jason Hernandez, Julie Hocknell and</p> <p>14 Heather Nonnenmann.</p> <p>15 Q. Okay. Now, Dan Smith, again, he was the</p> <p>16 inventor of the TVT-Secur?</p> <p>17 A. Correct.</p> <p>18 Q. And if you -- let's look at the section</p> <p>19 under "Scope Discussion and General Development</p> <p>20 Considerations."</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And what is noted next to</p> <p>24 Dan Smith's initials?</p>	<p>1 position for the treatment requirements necessary</p> <p>2 for the next generation mini-sling?</p> <p>3 MR. SNELL: Object; leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. It must be effective and must have</p> <p>6 clinical data.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And if we go to -- if you go to the</p> <p>9 section where Carl Nilsson discusses the efficacy</p> <p>10 and complications.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. What does Dr. Nilsson write concerning</p> <p>14 the efficacy and complications of the mini-slings?</p> <p>15 MR. SNELL: Object.</p> <p>16 BY THE WITNESS:</p> <p>17 A. There is no documentation that the</p> <p>18 mini-sling is safer and with equivalent efficacy of</p> <p>19 the TVT-Secur. It must get there, stay there and</p> <p>20 be tensioned properly.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Now, you had discussed the section about</p> <p>23 Carl Nilsson's treatment requirements that there</p> <p>24 must -- that it must be effective, safe and easy to</p>
Page 459	Page 461
<p>1 MR. SNELL: Objection; leading.</p> <p>2 BY THE WITNESS:</p> <p>3 A. "Intent for Next Generation Mini-Sling."</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And what was your understanding of this</p> <p>6 discussion and why it was occurring?</p> <p>7 A. To discuss the development of a new</p> <p>8 mini-sling.</p> <p>9 Q. Do you see next to CN, the initials</p> <p>10 CN -- strike that.</p> <p>11 Who is -- do you see the initials CN?</p> <p>12 A. Yes.</p> <p>13 Q. Is that Carl Nilsson?</p> <p>14 A. Yes.</p> <p>15 MR. SNELL: Object; leading. Go ahead.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Do you understand who the initials CN</p> <p>18 stands for?</p> <p>19 A. Carl Nilsson.</p> <p>20 Q. And do you see where it says "Treatment</p> <p>21 Requirements"?</p> <p>22 A. Yes.</p> <p>23 Q. What were Carl Nilsson's, based on this</p> <p>24 record, what were Carl Nilsson's or what was his</p>	<p>1 perform just a moment ago.</p> <p>2 Do you recall that?</p> <p>3 A. Yes.</p> <p>4 MR. SNELL: Objection; leading, misstates the</p> <p>5 testimony.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Was the TVT-Secur, in your opinion,</p> <p>8 effective or ineffective?</p> <p>9 MR. SNELL: Object.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Ineffective.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Was the TVT-Secur safe or unsafe, in</p> <p>14 your opinion?</p> <p>15 A. Unsafe.</p> <p>16 Q. Was the TVT-Secur easy to perform or</p> <p>17 hard to perform?</p> <p>18 A. Hard to perform.</p> <p>19 Q. Did the TVT-Secur meet the treatment</p> <p>20 requirements outlined by Carl Nilsson?</p> <p>21 MR. SNELL: Object.</p> <p>22 BY THE WITNESS:</p> <p>23 A. No.</p> <p>24 BY MR. THORNBURGH:</p>

28 (Pages 458 to 461)

Bruce Alan Rosenzweig, M.D.

Page 462	Page 464
<p>1 Q. Are -- now, if you go down to the</p> <p>2 section that talks about Carl Nilsson and the</p> <p>3 section is titled "Efficacy and Complications."</p> <p>4 Do you see that section?</p> <p>5 A. Yes.</p> <p>6 Q. Was there -- do you see where it says,</p> <p>7 "There is no documentation that mini-sling is safer</p> <p>8 and with equal efficacy as TVT"?</p> <p>9 A. Yes.</p> <p>10 MR. SNELL: Object; leading.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Do you agree with Dr. Nilsson that the</p> <p>13 mini-sling was not safer and specifically the</p> <p>14 TVT-Secur was not safer and did not have equal</p> <p>15 efficacy as the TVT?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What does Dr. Nilsson write with respect</p> <p>21 to the hammock procedure or the hammock approach of</p> <p>22 the TVT-Secur?</p> <p>23 MR. SNELL: Object.</p> <p>24 BY THE WITNESS:</p>	<p>1 tensioned properly"?</p> <p>2 MR. SNELL: Object; leading.</p> <p>3 BY THE WITNESS:</p> <p>4 A. He questions whether there will ever be</p> <p>5 a mini-sling that will work.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. If you go under "Model Development." Do</p> <p>8 you see that?</p> <p>9 A. Yes.</p> <p>10 Q. What does Dr. Nilsson say about cadaver</p> <p>11 work?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. That it is okay "but it is not the same</p> <p>15 as real tissue, resistance of the TVT-Secur is very</p> <p>16 different."</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Does that statement -- is there any</p> <p>19 significance to that statement with respect to your</p> <p>20 opinions?</p> <p>21 A. Yes.</p> <p>22 Q. What's that?</p> <p>23 A. That the design and development of the</p> <p>24 TVT-Secur based on cadaver models and sheep</p>
Page 463	Page 465
<p>1 A. It "will never work."</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Do you agree with Dr. Nilsson that the</p> <p>4 TVT-Secur hammock approach would never work?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Yes.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Did Ethicon ever tell -- based on</p> <p>10 your -- strike that.</p> <p>11 Based on your review of Ethicon's</p> <p>12 internal documents, did Ethicon ever disclose to</p> <p>13 the medical community that its Key Opinion Leader</p> <p>14 Dr. Nilsson, who had published and had spent</p> <p>15 considerable amount of his life researching the</p> <p>16 TVT Retropubic, that it was his opinion that the</p> <p>17 TVT-Secur mini-sling hammock approach would never</p> <p>18 work?</p> <p>19 MR. SNELL: Object.</p> <p>20 BY THE WITNESS:</p> <p>21 A. No.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What does Dr. Nilsson write after the</p> <p>24 section that says "Get there, stay there, can be</p>	<p>1 cadavers was not the same as real tissue. The</p> <p>2 resistance of TVT-Secur is very different.</p> <p>3 Q. If you turn the page to ETH.MESH ending</p> <p>4 in 516. What does David Smith -- sorry. Strike</p> <p>5 that.</p> <p>6 What does Dan Smith write concerning his</p> <p>7 meeting there with Dr. Nilsson?</p> <p>8 MR. SNELL: Object; leading.</p> <p>9 BY THE WITNESS:</p> <p>10 A. That with the next generation devices,</p> <p>11 "maybe the timeline should not be launch but rather</p> <p>12 run clinical trials 1, 2 and 3 before launch."</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Does that statement by Dan Smith have</p> <p>15 any significance to your opinions?</p> <p>16 A. Yes.</p> <p>17 Q. What?</p> <p>18 A. That there was inadequate clinical</p> <p>19 studies prior to the launch of the TVT-Secur.</p> <p>20 Q. How long has Ethicon, to your knowledge,</p> <p>21 and Johnson & Johnson been in business at this</p> <p>22 point in 2008?</p> <p>23 MR. SNELL: Objection.</p> <p>24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 466	Page 468
<p>1 A. That I don't specifically recall.</p> <p>2 MR. SNELL: Undisclosed.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Does it concern you at all that in 2008</p> <p>5 Dan Smith writes that maybe next time we should do</p> <p>6 studies before we launch the product?</p> <p>7 MR. SNELL: Objection and leading.</p> <p>8 BY THE WITNESS:</p> <p>9 A. That would be concerning, yes.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Why would it be concerning, Doctor?</p> <p>12 MR. SNELL: Same objections. Leading.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Because if the device is not studied</p> <p>15 clinically, then design characteristics of the</p> <p>16 device that make it unreasonably unsafe or</p> <p>17 unreasonably ineffective would not be known and,</p> <p>18 therefore, it would expose women to harms</p> <p>19 associated with those design characteristics that</p> <p>20 they would not be exposed to if the unsafe</p> <p>21 characteristics were known prior to launch.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Does it appear to you that Dan Smith is</p> <p>24 learning for the first time as an engineer that</p>	<p>1 in that section?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. "Working to block marketing of MiniArc</p> <p>5 in Finland for lack of clinical data - considered</p> <p>6 unethical."</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Do you agree that with -- do you agree</p> <p>9 with this statement that it would be unethical to</p> <p>10 launch a medical device without clinical data to</p> <p>11 support the launch?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Yes.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Do you agree that -- what's your</p> <p>17 understanding of Dr. Nilsson's statement that</p> <p>18 "People are allergic to six-week to six-month data,</p> <p>19 one year minimum data required"?</p> <p>20 MR. SNELL: Object.</p> <p>21 BY THE WITNESS:</p> <p>22 A. That six weeks or six months experience</p> <p>23 is not enough to determine the safety and efficacy</p> <p>24 of a medical device that is permanently implanted</p>
Page 467	Page 469
<p>1 before you launch a medical device into the</p> <p>2 worldwide market to be permanently implanted in</p> <p>3 patients that maybe you should test it first and</p> <p>4 make sure it's safe and effective?</p> <p>5 MR. SNELL: Objection and leading.</p> <p>6 BY THE WITNESS:</p> <p>7 A. The statement is, "Maybe the timeline</p> <p>8 should not be launch but rather, run clinicals 1, 2</p> <p>9 and 3."</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. What does Carl Nilsson -- how does Carl</p> <p>12 Nilsson respond to Dan Smith regarding the idea</p> <p>13 that maybe you should do studies before you launch</p> <p>14 a product?</p> <p>15 MR. SNELL: Objection and leading.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Carl Nilsson states people are allergic</p> <p>18 to six-week to six-month data. There should be a</p> <p>19 minimum of one-year data.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. What does the two -- do you see the two</p> <p>22 asterisks in that section?</p> <p>23 A. Yes.</p> <p>24 Q. What does Carl Nilsson write in that --</p>	<p>1 in a woman to treat stress urinary incontinence.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Do you agree with that statement?</p> <p>4 A. Yes.</p> <p>5 Q. If you go to the "Mesh Properties"</p> <p>6 section. Are you there?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And is there anything significant</p> <p>9 within this section with respect to your opinions?</p> <p>10 A. Yes. Dr. Nilsson states he will not use</p> <p>11 laser-cut mesh. It does not have the same stretch</p> <p>12 profile of mechanical-cut mesh, does not have -- it</p> <p>13 has different elasticity and fixation requirements.</p> <p>14 Q. In fact, it says, "Will not use</p> <p>15 laser-cut mesh!!" Right?</p> <p>16 A. Correct.</p> <p>17 MR. SNELL: Objection; leading.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Okay. Do you agree that laser-cut mesh</p> <p>20 would not work in a mini-sling like the TVT-Secur?</p> <p>21 MR. SNELL: Objection.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Laser cutting short mesh makes the mesh</p> <p>24 stiffer and more rigid and therefore is a design</p>

30 (Pages 466 to 469)

Bruce Alan Rosenzweig, M.D.

Page 470	Page 472
<p>1 characteristic that makes it unreasonably unsafe.</p> <p>2 MR. SNELL: Objection. Move to strike.</p> <p>3 Non-responsive.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. How does this statement by Dr. Nilsson</p> <p>6 that he would not use laser-cut mesh support your</p> <p>7 opinions, if at all?</p> <p>8 A. This supports my opinions that laser</p> <p>9 cutting a short mesh makes it unreasonably -- is a</p> <p>10 design characteristic that makes it unreasonably</p> <p>11 unsafe.</p> <p>12 Q. Are there any other statements in this</p> <p>13 document that support your opinions?</p> <p>14 A. Yes. This document supports my opinion</p> <p>15 that the training for the TVT-Secur device was</p> <p>16 inadequate and defective. Dr. Nilsson writes,</p> <p>17 "Huge complications in Germany with TVT-Secur</p> <p>18 because of training concerns and training is so</p> <p>19 poor in so many countries."</p> <p>20 It also supports my opinions about the</p> <p>21 arrow tip introducers being a design characteristic</p> <p>22 that is unreasonably unsafe. Dr. Nilsson states</p> <p>23 that "No cutting edge blade is a very good thing.</p> <p>24 Just maintain a tissue separator."</p>	<p>1 MR. SNELL: Objection; improper hypothetical,</p> <p>2 undisclosed. Go ahead.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Based on Dr. Nilsson's statement, 1,000.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Did, to your knowledge from your review</p> <p>7 of the medical -- strike that.</p> <p>8 To your knowledge from your review of</p> <p>9 Ethicon's internal documents, did Ethicon ever</p> <p>10 disclose to physicians who were deciding whether or</p> <p>11 not to switch to the TVT-Secur product to begin</p> <p>12 implanting patients with that new product that</p> <p>13 there was a 100-patient learning curve?</p> <p>14 MR. SNELL: Objection.</p> <p>15 BY THE WITNESS:</p> <p>16 A. No.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Based on your review of Ethicon's</p> <p>19 internal documents, did Ethicon ever disclose to</p> <p>20 patients -- to doctors that there was a 100-patient</p> <p>21 learning curve?</p> <p>22 MR. SNELL: Same objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. No.</p>
Page 471	Page 473
<p>1 Dr. Nilsson also supports my opinion</p> <p>2 that the IFU was defective and that the training</p> <p>3 was inadequate, stating that the learning curve for</p> <p>4 Dr. Nilsson was 100 patients before he was very</p> <p>5 good with very dry results.</p> <p>6 Q. Have you ever heard of any other medical</p> <p>7 device having a learning curve of 100 patients?</p> <p>8 MR. SNELL: Objection. Undisclosed.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Not that I recall.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. I mean, if ten -- there are more than</p> <p>13 ten surgeons in -- let me ask this question.</p> <p>14 Do you know how many urogynecologists</p> <p>15 and gynecologists live just here in Chicago?</p> <p>16 A. There are quite a few.</p> <p>17 Q. If there were just --</p> <p>18 MR. SNELL: Object; non-responsive.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Were there are just ten urogynecologists</p> <p>21 in one city, for example, who implant -- who</p> <p>22 decided to implant a TVT-Secur device, how many</p> <p>23 patients would they have to implant combined before</p> <p>24 they got over their learning curve?</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Did you review the IFU for the</p> <p>3 TVT-Secur?</p> <p>4 A. Yes, I did.</p> <p>5 Q. Did Ethicon ever disclose in the</p> <p>6 Instructions for Use that there would be a</p> <p>7 100-patient learning curve?</p> <p>8 A. No.</p> <p>9 MR. SNELL: Objection.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Patients who are the first -- first 99</p> <p>12 patients, are they at risk of experiencing adverse</p> <p>13 events as a result of being part of this</p> <p>14 100-patient learning curve?</p> <p>15 MR. SNELL: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Let me ask this question, Doctor.</p> <p>20 Do you have an opinion whether or not</p> <p>21 Ethicon should have told physicians that there was</p> <p>22 a 100-patient learning curve?</p> <p>23 MR. SNELL: Objection. Undisclosed.</p> <p>24 BY THE WITNESS:</p>

31 (Pages 470 to 473)

Bruce Alan Rosenzweig, M.D.

Page 474	Page 476
<p>1 A. Yes, they should have.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Is it reasonable that the TVT-Secur,</p> <p>4 according to this document, had a 100-patient</p> <p>5 learning curve?</p> <p>6 A. Can you repeat the question?</p> <p>7 Q. Is it reasonable, is it reasonable to</p> <p>8 sell a product, a device like the TVT-Secur, if it</p> <p>9 took 100 patients to get over the learning curve?</p> <p>10 MR. SNELL: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. For a device that treats stress urinary</p> <p>13 incontinence, no.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Does the fact that there was a</p> <p>16 100-patient learning curve have any significance to</p> <p>17 your opinions with respect to the design</p> <p>18 characteristics of the mesh -- of the TVT-Secur</p> <p>19 product?</p> <p>20 MR. SNELL: Object; leading.</p> <p>21 BY THE WITNESS:</p> <p>22 A. It supports my opinions that the</p> <p>23 Instructions for Use was defective. It supports my</p> <p>24 opinions that the training was inadequate. It</p>	<p>1 A. It supports my opinions that one of the</p> <p>2 design characteristics of the device, the short</p> <p>3 mesh, is a characteristic that is defectively</p> <p>4 designed and leads to unreasonable harm and</p> <p>5 unreasonable effectiveness.</p> <p>6 Q. Is there any other information in</p> <p>7 Exhibit 1128 that is significant to your opinions</p> <p>8 that you'd like to discuss with the ladies and</p> <p>9 gentlemen of the jury?</p> <p>10 A. No.</p> <p>11 Q. What's the next exhibit, Doctor?</p> <p>12 A. It is P2718.</p> <p>13 Q. And can you identify Exhibit P2718 to</p> <p>14 the jury, please?</p> <p>15 A. Yes. It is an e-mail string between key</p> <p>16 Ethicon employees; the Medical Director of Canada;</p> <p>17 David Robinson, Medical Director of the</p> <p>18 United States; and other key Ethicon employees.</p> <p>19 Q. And what opinions does Exhibit P2718</p> <p>20 support?</p> <p>21 A. It supports my opinions that the</p> <p>22 TVT-Secur was inadequately tested prior to launch;</p> <p>23 that there was inadequate study of the device</p> <p>24 during the design and development phase.</p>
Page 475	Page 477
<p>1 supports my opinions that the device was not</p> <p>2 studied during the design and the development</p> <p>3 phase. And it supports my opinions that there are</p> <p>4 design characteristics of the device that makes it</p> <p>5 unreasonably unsafe and unreasonably ineffective.</p> <p>6 MR. SNELL: Objection. Move to strike.</p> <p>7 Non-responsive, first two sentences of the answer.</p> <p>8 THE WITNESS: You're going to strike the first</p> <p>9 two sentences or the?</p> <p>10 MR. SNELL: The first two. I'm just moving on</p> <p>11 the first two that didn't concern design</p> <p>12 characteristics.</p> <p>13 THE WITNESS: Thank you.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. What did -- what length did Dr. Nilsson</p> <p>16 believe would be needed for a mini-sling that would</p> <p>17 be implanted through using the hammock approach?</p> <p>18 MR. SNELL: Objection.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Longer than 8 centimeters and he states</p> <p>21 ideally 14 centimeters.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. How does that support your opinions in</p> <p>24 this case, if at all?</p>	<p>1 Q. How does this document support those</p> <p>2 opinions?</p> <p>3 A. This is an e-mail regarding a</p> <p>4 notification of Johnson & Johnson by a Canadian</p> <p>5 newspaper about a story that they were going to</p> <p>6 write about the unethical issues regarding the new</p> <p>7 surgical device, the TVT-Secur.</p> <p>8 Q. If we -- if you turn to ETH.MESH number</p> <p>9 ending in 3170.</p> <p>10 MR. SNELL: I have to move to strike that last</p> <p>11 answer as non-responsive. Sorry, Dan.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Turn with me to ETH.MESH number ending</p> <p>14 in 3170. Are you there?</p> <p>15 A. Yes.</p> <p>16 Q. Do you see the -- do you see the e-mail</p> <p>17 from Russo-Jankewicz?</p> <p>18 A. Yes.</p> <p>19 Q. And is that an Ethicon employee in the</p> <p>20 United States?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And what does Jackie</p> <p>23 Russo-Jankewicz write in this e-mail?</p> <p>24 MR. SNELL: Objection; leading.</p>

Bruce Alan Rosenzweig, M.D.

Page 478	Page 480
<p>1 BY THE WITNESS:</p> <p>2 A. "Teresa, per our discussion, here's the</p> <p>3 standby we suggest. I'm copying David Robinson in</p> <p>4 our Medical Affairs group. David can you give this</p> <p>5 a read. Dave, I wanted to get this to Teresa</p> <p>6 Forester, PR director at J&J medical/Canada ASAP.</p> <p>7 We have been informed by our Canadian medical</p> <p>8 device manufacturer trade association that the</p> <p>9 National Post (Canadian newspaper) is working on a</p> <p>10 story regarding an article/commentary in June issue</p> <p>11 of Journal Obstetrics Gynecology Canada about</p> <p>12 ethical issues with new surgical devices (TVT-Secur</p> <p>13 is named)."</p> <p>14 Q. And if you go to the first page of 2718,</p> <p>15 what does David Robinson circulate to the other</p> <p>16 employees on this e-mail string?</p> <p>17 A. This is a standby statement to be given</p> <p>18 to outside agencies including the press.</p> <p>19 Q. And if you -- can you tell us what the</p> <p>20 standby statement says?</p> <p>21 MR. SNELL: Objection. Reading.</p> <p>22 BY THE WITNESS:</p> <p>23 A. "The TVT-Secur system is a midurethral</p> <p>24 sling device that maintains many of the key</p>	<p>1 With respect to the statement, "The</p> <p>2 device uses the same unique Prolene polypropylene</p> <p>3 mesh proven safe and effective with ten years of</p> <p>4 clinical data," is that a true or an untrue</p> <p>5 statement?</p> <p>6 MR. SNELL: Objection.</p> <p>7 BY THE WITNESS:</p> <p>8 A. It is the same Prolene polypropylene.</p> <p>9 However, the mesh is different. It is a shorter,</p> <p>10 stiffer, rigid, laser-cut mesh compared to the</p> <p>11 full-length TVT.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Go on, Doctor, to the next section.</p> <p>14 What does that section state?</p> <p>15 A. "Prior to marketing the TVT-Secur</p> <p>16 commercially available" -- excuse me.</p> <p>17 "Prior to making the TVT-Secur</p> <p>18 commercially available, we validated the safety of</p> <p>19 the device in clinical protocol (humans) in six</p> <p>20 sites in Europe and the U.S."</p> <p>21 Q. So, prior to -- did Ethicon -- strike</p> <p>22 that.</p> <p>23 Prior to making Gynecare TVT-Secur</p> <p>24 commercially available, did Ethicon validate the</p>
Page 479	Page 481
<p>1 elements that made the TVT the gold standard in SUI</p> <p>2 surgery. It optimizes safety and convenience</p> <p>3 through an innovative design that allows for a less</p> <p>4 invasive approach."</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Is that a true or an untrue statement,</p> <p>7 Doctor?</p> <p>8 MR. SNELL: Objection.</p> <p>9 BY THE WITNESS:</p> <p>10 A. It is not a true statement.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Go on, Doctor.</p> <p>13 A. "The TVT-Secur system features a small,</p> <p>14 compact design that facilitates an approach to</p> <p>15 incontinence that does not require exit incisions</p> <p>16 that can be performed under local anesthesia. With</p> <p>17 the device" -- excuse me. "The device uses the</p> <p>18 same unique Prolene polypropylene mesh proven safe</p> <p>19 and effective with ten years of clinical data. It</p> <p>20 has been used in over 1 million Gynecare TVT</p> <p>21 patients worldwide. The product was launched in</p> <p>22 September of 2006."</p> <p>23 Q. Let me stop you right there for a</p> <p>24 moment.</p>	<p>1 safety of the device in a clinical protocol human</p> <p>2 trial in six sites in Europe and the United States?</p> <p>3 MR. SNELL: Objection.</p> <p>4 BY THE WITNESS:</p> <p>5 A. No. They had data on 31 patients</p> <p>6 with -- through five weeks with a failure rate of</p> <p>7 approximately 30% and a complication rate of 60%.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Is that the first --</p> <p>10 MR. SNELL: Move to strike. Non-responsive.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Is that the First Human Use Study that</p> <p>13 we discussed yesterday?</p> <p>14 A. Correct.</p> <p>15 Q. Did the First Human Use Study validate</p> <p>16 the safety of the device before the TVT-Secur was</p> <p>17 launched?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No, it did not.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. So, is this a true or untrue statement,</p> <p>23 Doctor?</p> <p>24 A. This is not an accurate statement.</p>

Bruce Alan Rosenzweig, M.D.

Page 482	Page 484
<p>1 Q. The next -- what does the next bullet</p> <p>2 point say?</p> <p>3 A. "We sponsored the First Human Use Trial</p> <p>4 of the TVT-Secur device. This is a prospective,</p> <p>5 single-arm observational study of 70 patients with</p> <p>6 12 months follow-up. We expect the study to</p> <p>7 publish next year."</p> <p>8 Q. Is that the same study?</p> <p>9 A. Correct.</p> <p>10 Q. But the 12-month follow-up study instead</p> <p>11 of the interim analysis, is that correct?</p> <p>12 A. Correct.</p> <p>13 MR. SNELL: Object; leading.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. And did those results ultimately come</p> <p>16 out? Strike that.</p> <p>17 Did the 12 -- did Ethicon ultimately</p> <p>18 have available to them the data from the final</p> <p>19 12-month study?</p> <p>20 A. Ethicon had the data from the -- the</p> <p>21 final data from the 12-month study, yes.</p> <p>22 Q. And when they finally looked at the data</p> <p>23 from the 12-month study, did it validate the safety</p> <p>24 and efficacy of the device even post-launch?</p>	<p>1 concerning the First Human Use Study data that was</p> <p>2 available prior to launch, what would Ethicon need</p> <p>3 to disclose?</p> <p>4 MR. SNELL: Objection and leading.</p> <p>5 BY THE WITNESS:</p> <p>6 A. The data.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And what was that data?</p> <p>9 A. Prior to launch there was five-week data</p> <p>10 on 31 patients.</p> <p>11 Q. And what did that data show or</p> <p>12 demonstrate?</p> <p>13 A. A complication rate of approximately 60%</p> <p>14 and an incontinence rate of approximately 30%.</p> <p>15 Q. What's the next document in your binder,</p> <p>16 Doctor?</p> <p>17 A. This is an e-mail from Dan Smith dated</p> <p>18 November 13, 2008.</p> <p>19 Q. Before we get there, let me just go</p> <p>20 ahead and mark Exhibit 2707 for the record. Let me</p> <p>21 hand that to you.</p> <p>22 A. Thank you.</p> <p>23 MR. SNELL: Thank you.</p> <p>24 BY MR. THORNBURGH:</p>
Page 483	Page 485
<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. No, it did not.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And we'll talk about that in a little</p> <p>6 bit.</p> <p>7 MR. SNELL: Move to strike attorney comment.</p> <p>8 Go ahead.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Doctor, was this an opportunity that</p> <p>11 Ethicon had to tell the world about the results it</p> <p>12 had in the First Human Use Study before they</p> <p>13 launched the product?</p> <p>14 MR. SNELL: Object; form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. If Ethicon wanted it to be true, how</p> <p>19 would Ethicon have disclosed what the results were</p> <p>20 in the First Human Use interim analysis?</p> <p>21 MR. SNELL: Objection.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. In other words, if Ethicon wanted to</p> <p>24 provide a standby statement that was accurate</p>	<p>1 Q. Do you recognize that document?</p> <p>2 A. Yes.</p> <p>3 Q. What's that document?</p> <p>4 A. This is a --</p> <p>5 MR. SNELL: Hold on. I'm sorry. Which one</p> <p>6 are we talking about?</p> <p>7 MR. THORNBURGH: Exhibit 2707.</p> <p>8 MR. SNELL: Okay.</p> <p>9 BY THE WITNESS:</p> <p>10 A. This is a media standby statement with</p> <p>11 the tag "Do Not Distribute."</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Now, this is I think a final draft of</p> <p>14 the standby statement that we just looked at so I'm</p> <p>15 not going to go through the whole thing. There is</p> <p>16 just an additional statement in this standby</p> <p>17 statement that I want to discuss with you real</p> <p>18 quick.</p> <p>19 If you go down to the section that</p> <p>20 says, "If pressed."</p> <p>21 MR. SNELL: Move to strike the lawyer</p> <p>22 predicate.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Do you see that?</p>

Bruce Alan Rosenzweig, M.D.

Page 486	Page 488
<p>1 MR. SNELL: Leading.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. What does Ethicon say that, if pressed</p> <p>4 by the media, how they would respond further about</p> <p>5 why Ethicon decided to launch the TVT-Secur prior</p> <p>6 to the completion of the First Human Use clinical</p> <p>7 trial?</p> <p>8 MR. SNELL: Object. Sorry. Object; reading.</p> <p>9 Also this is not on his reliance list. Move to</p> <p>10 strike all questioning. Go ahead.</p> <p>11 MR. THORNBURGH: It is. Go ahead.</p> <p>12 BY THE WITNESS:</p> <p>13 A. "We believe Secur offers a compelling</p> <p>14 patient benefit - the potential for less</p> <p>15 postoperative pain and the ability to avoid the</p> <p>16 retropubic space. Because of this we made the</p> <p>17 decision to move forward" -- excuse me -- "to move</p> <p>18 ahead with a controlled launch supported by strong</p> <p>19 professional education programs."</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Doctor, is that a true statement?</p> <p>22 A. No.</p> <p>23 MR. SNELL: Object.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 A. P1676.</p> <p>2 MR. SNELL: Can I get a copy.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Can you identify this document for the</p> <p>5 ladies and gentlemen of the jury?</p> <p>6 A. Yes, this is an e-mail or a white paper</p> <p>7 from Dan Smith dated November 13, 2008.</p> <p>8 Q. What opinion does this -- sorry. What</p> <p>9 was the date again?</p> <p>10 A. November --</p> <p>11 Q. 13?</p> <p>12 A. -- 13, 2008.</p> <p>13 Q. Okay. And this is Dan Smith who was the</p> <p>14 project leader for the TVT-Secur?</p> <p>15 A. Correct.</p> <p>16 Q. And this is still while the TVT-Secur is</p> <p>17 being marketed and sold to patients around the</p> <p>18 world?</p> <p>19 A. Correct.</p> <p>20 Q. Including patients here in the Midwest?</p> <p>21 MR. SNELL: Object; leading.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Correct.</p> <p>24 BY MR. THORNBURGH:</p>
Page 487	Page 489
<p>1 Q. Based on your review of Ethicon's</p> <p>2 internal documents, why did Ethicon launch the</p> <p>3 TVT-Secur product prior to the completion of the</p> <p>4 12-month First Human Use Study?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. To be the first to market to maintain</p> <p>8 their market share.</p> <p>9 MR. SNELL: Move to strike. Intent answer.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Do you have an opinion about whether or</p> <p>12 not Ethicon was being truthful in its standby</p> <p>13 statement that it prepared for the media?</p> <p>14 MR. SNELL: Objection.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes, I have an opinion.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. What is that opinion?</p> <p>19 MR. SNELL: Same objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. That it's not completely accurate.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What's the next document you'd like to</p> <p>24 discuss, Doctor?</p>	<p>1 Q. Including patients who are in West</p> <p>2 Virginia?</p> <p>3 MR. SNELL: Objection; leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Correct.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Including patients who are in</p> <p>8 New Jersey?</p> <p>9 MR. SNELL: Objection; leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Correct.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Patients are still being implanted with</p> <p>14 the TVT-Secur product in California?</p> <p>15 MR. SNELL: Objection; leading.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Correct.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Patients are still being implanted with</p> <p>20 the TVT-Secur product in Philadelphia --</p> <p>21 MR. SNELL: Objection; leading.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. -- at this time?</p> <p>24 MR. SNELL: Objection; leading.</p>

35 (Pages 486 to 489)

Bruce Alan Rosenzweig, M.D.

Page 490	Page 492
<p>1 BY THE WITNESS:</p> <p>2 A. Correct.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. What opinions does Exhibit P1676</p> <p>5 support?</p> <p>6 A. It supports my opinions about the design</p> <p>7 characteristics of the TVT-Secur device that make</p> <p>8 it unreasonably unsafe or unreasonably ineffective.</p> <p>9 Q. What's the title of this document?</p> <p>10 A. "Things to consider as we assess next</p> <p>11 steps for a next generation sling."</p> <p>12 Q. Based on your review of Ethicon's</p> <p>13 internal documents, do you have an understanding as</p> <p>14 to why they were looking at things to consider as</p> <p>15 they were assessing the development of their next</p> <p>16 generation sling?</p> <p>17 MR. SNELL: Object.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Yes. The internal documents that I</p> <p>20 reviewed show that the TVT-Secur device at this</p> <p>21 point was felt to be a failed product line.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Did they tell patients that the</p> <p>24 TVT-Secur was a failed product line ever?</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. When doctors in Philadelphia at this</p> <p>3 time in 2008 were discussing options with their</p> <p>4 patients for treating their stress urinary</p> <p>5 incontinence, did Ethicon disclose to those doctors</p> <p>6 that internally Ethicon believed that the TVT-Secur</p> <p>7 was a failed product?</p> <p>8 MR. SNELL: Objection and leading. Go ahead.</p> <p>9 BY THE WITNESS:</p> <p>10 A. No.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. In West Virginia when urogynecologists</p> <p>13 and gynecologists were considering whether or not</p> <p>14 to use the TVT-Secur product at this time in 2008,</p> <p>15 did Ethicon ever disclose to those doctors that</p> <p>16 they internally at Ethicon believed the TVT-Secur</p> <p>17 was a failed product?</p> <p>18 MR. SNELL: Objection and leading.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Do you have opinion whether or not</p> <p>23 Ethicon and Johnson & Johnson should have disclosed</p> <p>24 to these doctors who were making these treatment</p>
Page 491	Page 493
<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. No.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. When patients in Philadelphia were being</p> <p>6 implanted with the TVT-Secur product at this time,</p> <p>7 did Ethicon say, "Hold on a second, patients. You</p> <p>8 might want to understand that it's our belief</p> <p>9 internally at Ethicon that the TVT-Secur is a</p> <p>10 failed product"?</p> <p>11 MR. SNELL: Object and leading.</p> <p>12 BY THE WITNESS:</p> <p>13 A. No.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Did it tell patients in West Virginia at</p> <p>16 this time, "Hold on, patients. When you're</p> <p>17 considering whether or not to undergo a procedure</p> <p>18 to treat your stress urinary incontinence, you need</p> <p>19 to know with respect to the TVT-Secur product we at</p> <p>20 Ethicon and Johnson & Johnson believe it is a</p> <p>21 failed product"?</p> <p>22 MR. SNELL: Objection and leading.</p> <p>23 BY THE WITNESS:</p> <p>24 A. No.</p>	<p>1 considerations that they believed internally that</p> <p>2 the TVT-Secur was a failed product?</p> <p>3 MR. SNELL: Objection; leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Yes, I have an opinion.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. What's that opinion?</p> <p>8 MR. SNELL: Same.</p> <p>9 BY THE WITNESS:</p> <p>10 A. That that should have been disclosed.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. What happens or what can happen to</p> <p>13 patients in Philadelphia if companies like</p> <p>14 Johnson & Johnson and Ethicon don't disclose</p> <p>15 information like this about their products?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Patients will be exposed to unreasonable</p> <p>19 harm.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. What can happen to patients in West</p> <p>22 Virginia if Ethicon and Johnson & Johnson don't</p> <p>23 disclose information like this?</p> <p>24 MR. SNELL: Object.</p>

36 (Pages 490 to 493)

Bruce Alan Rosenzweig, M.D.

Page 494	Page 496
<p>1 BY THE WITNESS:</p> <p>2 A. Patients will be exposed to unreasonable</p> <p>3 harm.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. What can happen to patients in Florida</p> <p>6 if Ethicon and Johnson & Johnson don't disclose</p> <p>7 information like this?</p> <p>8 MR. SNELL: Object.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Patients will be exposed to unreasonable</p> <p>11 harm.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. What could happen to patients in</p> <p>14 California and in Chicago and in Texas?</p> <p>15 A. They will be exposed to --</p> <p>16 MR. SNELL: Same.</p> <p>17 BY THE WITNESS:</p> <p>18 A. -- unreasonable harm.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What about -- what opinions does</p> <p>21 Exhibit P1676 support?</p> <p>22 MR. SNELL: Object; asked and answered. Go</p> <p>23 ahead.</p> <p>24 BY THE WITNESS:</p>	<p>1 of the mini-sling is sufficiently different than</p> <p>2 what surgeons are used to," demonstrating that the</p> <p>3 Instructions for Use is defective since it cannot</p> <p>4 describe for physicians how to appropriately</p> <p>5 tension the TVT-Secur.</p> <p>6 "Although we told surgeons how the</p> <p>7 TVT-Secur needed to be set, they just were not</p> <p>8 ready to believe us, the sales force was not</p> <p>9 confident due to early failures. We did not have</p> <p>10 data to support the thinking. We (and Ethicon)</p> <p>11 never before told surgeons how to set mesh tension</p> <p>12 because there was no one setting."</p> <p>13 This supports my opinions that the</p> <p>14 Instructions for Use is defective because it cannot</p> <p>15 accurately, reliably and reproducibly describe for</p> <p>16 surgeons how to set the tension because, as</p> <p>17 Dan Smith states, there is no one tension.</p> <p>18 This supports my opinion that training</p> <p>19 was defective.</p> <p>20 As Dan Smith writes, "Most surgeons are</p> <p>21 unfamiliar with the anatomy. Most surgeons have no</p> <p>22 idea as to the dynamics of the sling nor that TVT</p> <p>23 (tension-free tape) is actually not tension-free</p> <p>24 and never was."</p>
Page 495	Page 497
<p>1 A. It supports my opinion that the</p> <p>2 TVT-Secur mesh, the short, stiff, rigid mesh, is</p> <p>3 too short; the Instructions for Use is defective;</p> <p>4 that the training was inadequate.</p> <p>5 Q. How does Exhibit 1676 support that</p> <p>6 opinion, Doctor?</p> <p>7 A. First, Dan Smith states, "Mini-slugs</p> <p>8 have the potential to own a large potential of the</p> <p>9 market once surgeons understand how to set the</p> <p>10 tension."</p> <p>11 That supports my opinion that the</p> <p>12 Instructions for Use is defective since it cannot</p> <p>13 explain to surgeons how to tension the TVT-Secur</p> <p>14 device.</p> <p>15 Number two, the "TVT-Secur device should</p> <p>16 have been launched as two separate products, the U</p> <p>17 being 8 centimeters and the H being 10 centimeters</p> <p>18 and having their own Instructions for Use."</p> <p>19 This supports my opinion that the</p> <p>20 Instructions for Use is defective and that the</p> <p>21 TVT-Secur in the H position is too short, being a</p> <p>22 design characteristic which makes it unreasonably</p> <p>23 unsafe.</p> <p>24 The -- Mr. Smith continues, "The tension</p>	<p>1 Q. Hold on a second, Doctor. Hold that box</p> <p>2 up again for the ladies and gentlemen of the jury,</p> <p>3 please.</p> <p>4 MR. SNELL: Before you ask the question, I</p> <p>5 just need to move to strike part of the last answer</p> <p>6 with regard to the undisclosed opinion about the</p> <p>7 TVT hammock needing to be 10 centimeters. That's</p> <p>8 not in his report. Go ahead.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Go ahead, Doctor.</p> <p>11 A. This describes the box that the</p> <p>12 TVT-Secur comes in states that it is a tension-free</p> <p>13 support for incontinence.</p> <p>14 Q. So, according to Ethicon Dan Smith's own</p> <p>15 document, is this statement on Ethicon's -- on the</p> <p>16 box that the TVT-Secur came in that the TVT-Secur</p> <p>17 was tension-free support system, was that true?</p> <p>18 A. No.</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. How many untruths does there have to be</p> <p>22 before we call Johnson & Johnson a liar?</p> <p>23 MR. SNELL: Objection; leading, argumentative,</p> <p>24 undisclosed opinion, et cetera. Go ahead.</p>

37 (Pages 494 to 497)

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 498</p> <p>1 BY THE WITNESS:</p> <p>2 A. I don't think I can answer that</p> <p>3 question.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Fair enough, Doctor.</p> <p>6 If Ethicon knew that the TVT-Secur was</p> <p>7 not tension-free, not a tension-free system, was it</p> <p>8 appropriate for Ethicon to write on their -- on the</p> <p>9 box that the product came in that the TVT-Secur was</p> <p>10 a tension-free system?</p> <p>11 MR. SNELL: Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. That is not accurate.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Go ahead.</p> <p>16 A. The next that supports my opinion about</p> <p>17 laser cutting. "Most surgeons who use TVT products</p> <p>18 do not know if what they use contains</p> <p>19 mechanical-cut or laser-cut mesh. Additionally,</p> <p>20 they do not know we have laser-cut TVT and TVT-O</p> <p>21 products on the market."</p> <p>22 Q. How does that support your opinion, if</p> <p>23 at all?</p> <p>24 A. It supports my opinion that training was</p>	<p style="text-align: right;">Page 500</p> <p>1 mechanically-cut TVT-O or even as much as the</p> <p>2 full-length laser-cut TVT-O meshes."</p> <p>3 Did I read that correctly?</p> <p>4 MR. SNELL: Object; leading.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And can you just explain just a little</p> <p>9 bit slower how that statement by Dan Smith supports</p> <p>10 your opinion?</p> <p>11 MR. SNELL: Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. This documents that the shorter</p> <p>14 laser-cut TVT-Secur is stiffer, more rigid than</p> <p>15 full-length laser-cut or mechanical-cut mesh.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And is Dan Smith's own statement here</p> <p>18 consistent with your opinions?</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Yes.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Go ahead, Doctor.</p> <p>24 What does Dan Smith say about the length</p>
<p style="text-align: right;">Page 499</p> <p>1 inadequate to disclose the differences between</p> <p>2 laser-cut and mechanical-cut mesh to physicians.</p> <p>3 Q. Go ahead, Doctor.</p> <p>4 A. This also supports my opinions that</p> <p>5 short laser-cut mesh is too stiff, which is a</p> <p>6 design characteristic that leads to -- makes it</p> <p>7 unreasonably unsafe.</p> <p>8 The short laser-cut mesh does not have</p> <p>9 the same stretch as the full-length mechanical-cut</p> <p>10 TVT-O or as much as the full-length laser-cut</p> <p>11 TVT-O.</p> <p>12 Q. Okay. And if we -- can you just direct</p> <p>13 us to where in this document you're referring to.</p> <p>14 A. That is on ETH.MESH.1297, "Discussion</p> <p>15 regarding possible options using Mini-me."</p> <p>16 MR. THORNBURGH: And go ahead, Tom, if you can</p> <p>17 pull that up.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Is that the second bullet point under</p> <p>20 "Discussions regarding possible options using</p> <p>21 Mini-me"?</p> <p>22 A. Yes.</p> <p>23 Q. And it says, "The shorter laser-cut mesh</p> <p>24 does not stretch the same as the full-length</p>	<p style="text-align: right;">Page 501</p> <p>1 of the mesh -- what does Dan Smith say the length</p> <p>2 of the mesh should be based on some cadaver works</p> <p>3 that were done internally at Ethicon?</p> <p>4 MR. SNELL: Objection; leading.</p> <p>5 BY THE WITNESS:</p> <p>6 A. That the mesh should be 12 centimeters</p> <p>7 and that it should have some sort of fixation end</p> <p>8 to reduce the possibility of movement prior to</p> <p>9 tissue ingrowth. That supports my opinion that one</p> <p>10 of the design characteristics of the TVT-Secur,</p> <p>11 being the short, stiff, rigid mesh, and the fleece</p> <p>12 tips, were defectively designed and led to</p> <p>13 unreasonable harm being -- increasing complications</p> <p>14 or decreasing efficacy.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Anything else in this document, Doctor?</p> <p>17 A. No.</p> <p>18 Q. What's the next exhibit, Doctor?</p> <p>19 A. It is P1464.</p> <p>20 Q. And can you identify P1464 to the jury,</p> <p>21 please.</p> <p>22 A. Yes. It is an e-mail string from</p> <p>23 January 28, 2009.</p> <p>24 Q. And what opinions does Exhibit P1464</p>

Bruce Alan Rosenzweig, M.D.

Page 502	Page 504
<p>1 support?</p> <p>2 A. It supports my opinion that the</p> <p>3 TVT-Secur was inadequately studied prior to launch.</p> <p>4 Q. And how does it support that opinion,</p> <p>5 Doctor?</p> <p>6 A. This is an e-mail string between Piet</p> <p>7 Hinoul, Medical Director in France, and Judi Gauld</p> <p>8 from Ethicon in Great Britain; and it's discussing</p> <p>9 the data from the TVT-WORLD study, which is a</p> <p>10 registry that collected data on various</p> <p>11 incontinence products from Ethicon, including the</p> <p>12 TVT, the TVT-O and the TVT-Secur.</p> <p>13 Q. What does Dr. Hinoul write concerning</p> <p>14 the adverse events that he received from the</p> <p>15 TVT-WORLD?</p> <p>16 MR. SNELL: Move to strike prior answer as</p> <p>17 non-responsive.</p> <p>18 BY THE WITNESS:</p> <p>19 A. "This is pretty awful. Obviously there</p> <p>20 are a lot of investigators who mistake adverse</p> <p>21 outcomes for adverse events. Certain centers have</p> <p>22 a very high erosion rate it appears for continence</p> <p>23 tapes. I would not ask investigators if they would</p> <p>24 change, tell them you will change unless they</p>	<p>1 and the data should not be changed or manipulated</p> <p>2 in any way.</p> <p>3 MR. THORNBURGH: Now is probably a good time</p> <p>4 for a lunch break.</p> <p>5 MR. SNELL: I have to use the restroom. I</p> <p>6 was waiting.</p> <p>7 THE VIDEOGRAPHER: The time is 12:13 p.m.</p> <p>8 This is the end of Tape 2 and we're going off the</p> <p>9 video record.</p> <p>10 (WHEREUPON, the following</p> <p>11 proceedings were had off the video</p> <p>12 record:)</p> <p>13 MR. SNELL: Before we go off the stenographic</p> <p>14 record, just note on P2707, move to strike</p> <p>15 undisclosed opinions regarding that document as</p> <p>16 well.</p> <p>17 (WHEREUPON, a recess was had</p> <p>18 from 12:13 to 1:21 p.m.)</p> <p>19 (WHEREUPON, the following</p> <p>20 proceedings were had on the video</p> <p>21 record:)</p> <p>22 THE VIDEOGRAPHER: The time is 1:21 p.m. This</p> <p>23 is the beginning of Tape 3 and we are back on the</p> <p>24 video record.</p>
Page 503	Page 505
<p>1 object. It seems a lot of work for a registry to</p> <p>2 me, both for you and the investigators."</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. And who is Colin Urquhart? Is Colin an</p> <p>5 employee at Ethicon?</p> <p>6 A. Yes. From Ethicon Great Britain.</p> <p>7 Q. Is it, in your opinion, appropriate for</p> <p>8 employees of Ethicon to change clinical data</p> <p>9 results in a registry without asking permission?</p> <p>10 MR. SNELL: Objection.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Strike that.</p> <p>13 Is it okay for Ethicon employees to</p> <p>14 themselves change the data in a registry without</p> <p>15 having the doctors or the investigators do that on</p> <p>16 their own?</p> <p>17 MR. SNELL: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. No, it is not.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Why not?</p> <p>22 A. Because the information that is derived</p> <p>23 from the clinical study must be presented and</p> <p>24 published in its most complete and accurate status</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Good afternoon, Doctor.</p> <p>3 A. Good afternoon.</p> <p>4 Q. Doctor, what's the next tab in your</p> <p>5 binder that you'd like to discuss with the ladies</p> <p>6 and gentlemen of the jury?</p> <p>7 A. P2041.</p> <p>8 Q. What is P -- can you identify for the</p> <p>9 ladies and gentlemen of the jury what P4021 is?</p> <p>10 A. 2041. It's an e-mail from Dr. Aaron</p> <p>11 Kirkemo, a Medical Director at Ethicon, to other</p> <p>12 Ethicon employees.</p> <p>13 Q. How does Exhibit 2041 support your</p> <p>14 opinion?</p> <p>15 MR. SNELL: One second. Can I get a copy.</p> <p>16 MR. THORNBURGH: I'm looking for my copy.</p> <p>17 BY THE WITNESS:</p> <p>18 A. We can then skip that if people don't</p> <p>19 have it and move on to the next exhibit.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Did you get the Bates number right? Is</p> <p>22 there two stickers on it maybe?</p> <p>23 A. 0241, the Bates number ends in 1482.</p> <p>24 But it's not an important document.</p>

Bruce Alan Rosenzweig, M.D.

Page 506	Page 508
<p>1 Q. What's the next one in your binder, next</p> <p>2 tab?</p> <p>3 A. 0086.</p> <p>4 Q. And can you identify Exhibit 0086 for</p> <p>5 the record, please?</p> <p>6 A. Yes, this is a PowerPoint presentation</p> <p>7 from the TVT-WORLD registry presented on March 2,</p> <p>8 2009.</p> <p>9 Q. And what opinions does --</p> <p>10 MR. SNELL: Can I get copy.</p> <p>11 MR. THORNBURGH: Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. What opinion does Exhibit 86 -- P0086</p> <p>14 support?</p> <p>15 A. Supports my opinion that there were no</p> <p>16 long-term -- there was no human data prior to the</p> <p>17 launch of the TVT-Secur.</p> <p>18 Q. Well, there was the interim analysis, is</p> <p>19 that correct?</p> <p>20 A. Correct. There was no long-term human</p> <p>21 data to support the launch of TVT-Secur.</p> <p>22 Q. And how does Exhibit P0086 support that</p> <p>23 opinion?</p> <p>24 A. Under the slide "Some history," it</p>	<p>1 MR. SNELL: Same objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes, that is an accurate statement.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And the next -- I think you said the</p> <p>6 next statement on this slide was the decision not</p> <p>7 to start RCTs was due to budget constraints. Is</p> <p>8 that -- did I understand you correctly?</p> <p>9 MR. SNELL: Leading. Go ahead.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Correct.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And how does that statement support your</p> <p>14 opinions?</p> <p>15 A. That there was inadequate studies done</p> <p>16 prior to the launch of the device to be able to</p> <p>17 determine the characteristics of the device that</p> <p>18 were unsafe or made the device ineffective.</p> <p>19 Q. And are there any other -- any other</p> <p>20 information in this exhibit that support your</p> <p>21 opinions?</p> <p>22 A. Under "Commercial Summary." It's</p> <p>23 towards the end of the...</p> <p>24 Q. And what about this slide under the</p>
Page 507	Page 509
<p>1 describes that the TVT-Secur was launched in</p> <p>2 September of 2006.</p> <p>3 Q. And what slide are you on?</p> <p>4 A. Called "Some history." I think it's the</p> <p>5 second slide.</p> <p>6 Q. And do you know the date of this</p> <p>7 document?</p> <p>8 A. Yes. It is March 2, 2009.</p> <p>9 Q. Okay. And go ahead, Doctor. How does</p> <p>10 this exhibit support your opinion?</p> <p>11 A. The slide states that there was no</p> <p>12 long-term human use data to support the launch and</p> <p>13 the decision not to start a randomized controlled</p> <p>14 trial was due to budget constraints.</p> <p>15 Q. And do you have any opinions with</p> <p>16 respect to the statement that there were no --</p> <p>17 there was "no long-term human use data to support</p> <p>18 launch"?</p> <p>19 MR. SNELL: Objection.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Sorry. Do you have any opinions with</p> <p>22 respect to the statement in this document that</p> <p>23 there were "no long-term human use data to support</p> <p>24 launch"?</p>	<p>1 "Commercial Summary" section is significant to your</p> <p>2 opinions?</p> <p>3 A. It supports my opinions that there are</p> <p>4 design characteristics of the TVT-Secur that make</p> <p>5 it unreasonably unsafe and unreasonably</p> <p>6 ineffective.</p> <p>7 This states that the voice of consumers,</p> <p>8 which are doctors that are using the device, shows</p> <p>9 that barriers to the use of the TVT-Secur device</p> <p>10 include ease of use, meaning that it is not easy to</p> <p>11 use; that one of the complications that is seen is</p> <p>12 bleeding; and the final barrier is reproducibility,</p> <p>13 meaning that it is not effective in the treatment</p> <p>14 of stress urinary incontinence.</p> <p>15 So, there are design characteristics</p> <p>16 that make it unreasonably ineffective for the</p> <p>17 treatment of stress urinary incontinence.</p> <p>18 Q. Doctor, the fact that it was -- the fact</p> <p>19 that doctors were unable to reproduce the same</p> <p>20 results, does that indicate to you that the</p> <p>21 TVT-Secur was or was not defective?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. It demonstrates that both the device and</p>

Bruce Alan Rosenzweig, M.D.

Page 510	Page 512
<p>1 the Instructions for Use were defective. 2 BY MR. THORNBURGH: 3 Q. And what other slide in this exhibit 4 supports your opinions, if any? 5 A. None. 6 Q. Okay. What's the next tab number that 7 you'd like to discuss? 8 A. P1677. 9 Q. What's the tab just so I know for the 10 record? 11 A. 45. 12 Q. And did you say that was Exhibit P1677? 13 A. Yes. 14 Q. Can you identify for the ladies and 15 gentlemen of the jury what this exhibit is? 16 A. Yes. It's an internal Ethicon document. 17 It's a PowerPoint presentation regarding the next 18 generation slings. 19 Q. How does this exhibit support your 20 opinions? 21 A. It supports my opinion that the 22 TVT-Secur was not studied adequately prior to 23 launch. 24 Q. And what slide in this exhibit, what</p>	<p>1 BY THE WITNESS: 2 A. Yes. "What will be our position should 3 MiniArc (or any other exitless sling) get the same 4 efficacy as TVT-O, TVT." 5 BY MR. THORNBURGH: 6 Q. Actually, if you go up to the first 7 bullet point. 8 A. Okay. 9 Q. And read the second hash mark. 10 MR. SNELL: Same objections. 11 BY THE WITNESS: 12 A. "After our 'risky' situation with 13 TVT-Secur and increased demand for one year data." 14 BY MR. THORNBURGH: 15 Q. What's your understanding of that 16 statement? 17 MR. SNELL: Object. 18 BY THE WITNESS: 19 A. Not having data prior to the launch of 20 TVT-Secur put them in a risky situation or, 21 actually, put patients in a risky situation; that 22 all of the design characteristics that made the 23 TVT-Secur unreasonably unsafe or unreasonably 24 ineffective were not known due to the lack of</p>
Page 511	Page 513
<p>1 slide are you referring to that supports that 2 opinion? 3 A. It's a slide entitled "Watch Out." And 4 it's about halfway down or maybe three-quarters of 5 the way down the slide deck, right before the 6 backup slides, almost the very end of the 7 presentation. 8 MR. THORNBURGH: Okay. And can you pull that 9 up. You don't have it. Okay. 10 BY MR. THORNBURGH: 11 Q. What about this slide called "Watch Out" 12 supports your opinions? 13 A. It documents that not having long-term 14 or even one-year randomized control data put the 15 TVT-Secur in a, quote-unquote, "risky situation." 16 Q. And, so, if we look at this slide, what 17 does the first bullet point say? 18 A. "Are we willing to go to market with 12 19 months of randomized controlled data from only the 20 inventor's site?" 21 Q. And if you could read the second bullet 22 point under that bullet point, the hash mark. 23 MR. SNELL: Object; leading, reading. Go 24 ahead.</p>	<p>1 adequate testing and studying of the device. 2 And the risky situation were that 3 patients were exposed to risks and harms that would 4 have been found, determined if the device had been 5 studied. 6 Q. Is there any other slide in that exhibit 7 that you want to discuss? 8 A. No. 9 Q. What's the next tab in Exhibit 5 that 10 you want to discuss with the ladies and gentlemen 11 of the jury? 12 A. Tab 46, P number 2670. 13 Q. Can you identify that exhibit for the 14 ladies and gentlemen of the jury? 15 A. It is an e-mail string between key 16 Ethicon employees, including David Robinson, 17 Medical Director; Piet Hinoul, Medical Director; 18 and Bart Pattysen, professional education director 19 worldwide. 20 Q. And how does Exhibit 2670 support your 21 opinion? 22 A. It supports -- 23 Q. Strike that. 24 What opinion does this exhibit support?</p>

41 (Pages 510 to 513)

Bruce Alan Rosenzweig, M.D.

Page 514	Page 516
<p>1 A. That the TVT-Secur was inadequately</p> <p>2 studied prior to launch.</p> <p>3 Q. And what's the date of Exhibit 2670?</p> <p>4 A. May 13, 2009.</p> <p>5 Q. And what opinion does this exhibit</p> <p>6 support?</p> <p>7 A. Well, this supports my opinions about</p> <p>8 the design characteristics of the device that make</p> <p>9 the TVT-Secur unreasonably unsafe or unreasonably</p> <p>10 ineffective.</p> <p>11 Q. How does this exhibit support your</p> <p>12 opinion?</p> <p>13 A. It is describing a slide deck that was</p> <p>14 available for presentation and a discussion about</p> <p>15 which doctors this slide deck would be appropriate</p> <p>16 for.</p> <p>17 Q. Okay. Now, if you go to</p> <p>18 ETH.MESH.00815355.</p> <p>19 A. Yes.</p> <p>20 Q. And what does Piet Hinoul write in this</p> <p>21 e-mail?</p> <p>22 MR. SNELL: Object. Move to strike the prior</p> <p>23 answer at 148:8. Non-responsive.</p> <p>24 BY THE WITNESS:</p>	<p>1 A. I believe so.</p> <p>2 Q. And is it appropriate for companies like</p> <p>3 Ethicon to withhold slide decks concerning risk</p> <p>4 information of their products from Key Opinion</p> <p>5 Leaders such as Dr. Sepulveda?</p> <p>6 MR. SNELL: Object; misstates evidence.</p> <p>7 BY THE WITNESS:</p> <p>8 A. No.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And do you know whether or not</p> <p>11 Dr. Sepulveda was at this point in time training</p> <p>12 physicians on the TVT-Secur device?</p> <p>13 A. Yes.</p> <p>14 Q. And was he?</p> <p>15 A. Yes.</p> <p>16 Q. If Dr. Sepulveda is not provided with</p> <p>17 important safety and efficacy information</p> <p>18 concerning the TVT-Secur device, do you know</p> <p>19 whether or not that impedes his ability to share</p> <p>20 the information that Ethicon has internally with</p> <p>21 the doctors that he's training?</p> <p>22 MR. SNELL: Object; misstates evidence.</p> <p>23 BY THE WITNESS:</p> <p>24 A. That would impede his ability to share</p>
Page 515	Page 517
<p>1 A. "I have a meeting with James Sepulveda</p> <p>2 in two weeks in Europe for a couple of TVT-Secur</p> <p>3 and Prolift prof ed events. He asked if I can</p> <p>4 share with him some numbers you shared with the</p> <p>5 preceptors at the Pelvic Floor Summit. I believe</p> <p>6 he was specifically thinking about a very powerful</p> <p>7 slide that you showed about how many Prolift</p> <p>8 procedures have been performed versus other</p> <p>9 devices, perhaps?"</p> <p>10 Q. How does -- what does Dr. Hinoul</p> <p>11 respond? What's Dr. Hinoul's respond to this</p> <p>12 e-mail?</p> <p>13 MR. SNELL: Object; reading.</p> <p>14 BY THE WITNESS:</p> <p>15 A. "I did not read the end of your mail. I</p> <p>16 thought you wanted to see the slides. I'm not</p> <p>17 happy for you to forward this slide deck to</p> <p>18 Dr. Sepulveda. I hope you understand."</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. And who is Dr. Sepulveda?</p> <p>21 A. Dr. Sepulveda is a pelvic surgeon and</p> <p>22 Key Opinion Leader.</p> <p>23 Q. And are you aware that he's an expert in</p> <p>24 this case?</p>	<p>1 that information with doctors he is training.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Now, there's a response from Bart</p> <p>4 Pattyson to Dr. Hinoul. Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. And do you know who Bart Pattyson is?</p> <p>7 A. Yes. He is the professional education</p> <p>8 director worldwide for Ethicon.</p> <p>9 Q. And what does Bart Pattyson write to</p> <p>10 Dr. Hinoul?</p> <p>11 MR. SNELL: Object; reading.</p> <p>12 BY THE WITNESS:</p> <p>13 A. "I think we as a company are long</p> <p>14 overdue in providing the world with a status check</p> <p>15 on the TVT-Secur. The good, the bad and the</p> <p>16 (hopefully not too) ugly."</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Is it important for companies such as</p> <p>19 Ethicon to provide all the information about its</p> <p>20 medical devices, including not only the good but</p> <p>21 also the bad and the ugly?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes.</p>

42 (Pages 514 to 517)

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 518</p> <p>1 BY MR. THORNBURGH:</p> <p>2 Q. If Ethicon does not communicate with the</p> <p>3 doctors who they are promoting the TVT-Secur to</p> <p>4 about the good, the bad and the ugly, does that put</p> <p>5 patients at risk?</p> <p>6 MR. SNELL: Object; leading.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. In what way?</p> <p>11 MR. SNELL: Same.</p> <p>12 BY THE WITNESS:</p> <p>13 A. If doctors are not told about the risks</p> <p>14 of the device, the characteristics of the device</p> <p>15 that make it unreasonably unsafe or unreasonably</p> <p>16 ineffective, they cannot make an appropriate</p> <p>17 decision about using that device in the treatment</p> <p>18 of patients.</p> <p>19 They cannot also pass the information on</p> <p>20 about the risks associated with the device to</p> <p>21 patients in order for the patient to make an</p> <p>22 informed decision.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Is there any other information in</p>	<p style="text-align: right;">Page 520</p> <p>1 A. The slide deck under the title</p> <p>2 page "TVT-Secur" lists the reasons why the success</p> <p>3 rate was lower, which includes the shorter tape;</p> <p>4 may impact the pull-out forces, which demonstrates</p> <p>5 that the short stiff mesh; and the fleece tips, the</p> <p>6 mesh was too short, the fleece tips were -- did not</p> <p>7 hold; and that led to the harm of either not being</p> <p>8 able to treat the stress incontinence or led to</p> <p>9 recurrent stress incontinence.</p> <p>10 Q. Do you know whether or not -- do you</p> <p>11 have an opinion whether or not it was appropriate</p> <p>12 for Piet Hinoul at Ethicon to withhold from</p> <p>13 Dr. Sepulveda information concerning the mesh</p> <p>14 characteristics which were leading to a lower</p> <p>15 success rate for the product?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY THE WITNESS:</p> <p>18 A. No.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Do you have a -- do you have an opinion?</p> <p>21 A. Yes, I have an opinion.</p> <p>22 Q. What's the opinion?</p> <p>23 MR. SNELL: Same objection.</p> <p>24 BY THE WITNESS:</p>
<p style="text-align: right;">Page 519</p> <p>1 Exhibit 2670 that is relevant to your opinions?</p> <p>2 A. No.</p> <p>3 Q. And have you actually had an opportunity</p> <p>4 to review the slide deck that was attached to</p> <p>5 Exhibit 2670 to the e-mail exchange?</p> <p>6 A. Yes.</p> <p>7 Q. And did you review and rely on that</p> <p>8 e-mail?</p> <p>9 A. Yes.</p> <p>10 Q. And what about Exhibit -- strike that.</p> <p>11 What's the exhibit number?</p> <p>12 A. It is P28 -- excuse me. 2688.</p> <p>13 Q. And can you identify this document for</p> <p>14 the ladies and gentlemen of the jury?</p> <p>15 A. It is a slide deck from Ethicon's</p> <p>16 internal files.</p> <p>17 Q. And what opinions does this slide deck,</p> <p>18 Exhibit 2688, support?</p> <p>19 A. This supports my opinions that there are</p> <p>20 design characteristics of the TVT-Secur that make</p> <p>21 it unreasonably unsafe and unreasonably ineffective</p> <p>22 in treating women with stress urinary incontinence.</p> <p>23 Q. And what about Exhibit -- or how does</p> <p>24 Exhibit 2688 support that opinion?</p>	<p style="text-align: right;">Page 521</p> <p>1 A. That they should not withhold that</p> <p>2 information.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. And is the information written here by</p> <p>5 Dr. Hinoul concerning the design characteristics</p> <p>6 consistent with your opinions about the design</p> <p>7 defects with the TVT-Secur product?</p> <p>8 MR. SNELL: Object; leading.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Yes.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Is there any other information you'd</p> <p>13 like to discuss at this time concerning</p> <p>14 Exhibit 2688?</p> <p>15 A. Again, this describes the defects of the</p> <p>16 short tape, the fleece tips, the wide, sharp arrow</p> <p>17 tip introducer, the lack -- or the defect in the</p> <p>18 Instructions for Use as there is no guide. But</p> <p>19 after that, no.</p> <p>20 Q. Okay. What's the next document you'd</p> <p>21 like to discuss?</p> <p>22 A. It is tab 48. It is P1008.</p> <p>23 Q. And can you identify this document for</p> <p>24 the ladies and gentlemen of the jury?</p>

43 (Pages 518 to 521)

Bruce Alan Rosenzweig, M.D.

Page 522	Page 524
<p>1 A. Yes. It is an internal Ethicon 2 document. It is a slide deck from the Women's -- 3 Ethicon's Women's Health and Urology Brand Equity 4 Study from January of 2010. 5 Q. What opinions does this exhibit support? 6 A. It supports my opinions that Ethicon 7 failed to adequately study the TVT-Secur prior to 8 launch. 9 Q. And how does it support that opinion? 10 A. This document, one of the slides states, 11 "To some, Ethicon is guilty of two cardinal sins 12 relating to surgical products. A rush to market in 13 the absence of sound data for the TVT-Secur." 14 MR. SNELL: Object. Move to strike. Reading. 15 MR. THORNBURGH: And if we can, go ahead and 16 go to that slide, Tom. It starts with "To some, 17 Ethicon is guilty of two cardinal sins." 18 BY MR. THORNBURGH: 19 Q. Go ahead, Doctor. What does this slide 20 discuss with respect to the TVT-Secur? 21 MR. SNELL: Object. 22 BY THE WITNESS: 23 A. Number one, that the Secur was rushed to 24 market. Number two, that there was no -- it was</p>	<p>1 A. No. 2 Q. What's the next exhibit, Doctor? 3 A. It is P0934. 4 MR. SNELL: While Mr. Thornburgh is getting 5 that, I will just object to P2688 as not on the 6 reliance list produced for Dr. Rosenzweig with his 7 reports and, therefore, move to strike all 8 questions. 9 MR. THORNBURGH: It is on his reliance list 10 and he has testified and was cross-examined on this 11 very document in two trials. 12 BY MR. THORNBURGH: 13 Q. I'm sorry. What was the next exhibit, 14 Doctor? 15 A. P0934. 16 Q. And can you identify for the jury what 17 this exhibit is? 18 A. This is the First Human Use Trial, the 19 six and 12-month data, draft version of the 20 clinical summary from that data. 21 Q. Okay. And is this the First Human Use 22 Study? 23 A. Yes. 24 Q. And is this the study that we've been</p>
Page 523	Page 525
<p>1 inadequately studied prior to launch. 2 BY MR. THORNBURGH: 3 Q. Do you agree with this statement in this 4 Ethicon company document that "Ethicon is guilty of 5 two cardinal sins relating to surgical products, a 6 rush to market in the absence of sound data 7 regarding the TVT-Secur"? 8 MR. SNELL: Object and leading. 9 BY THE WITNESS: 10 A. Yes. 11 BY MR. THORNBURGH: 12 Q. And are those your words, Doctor? 13 A. No, those are the words of the key 14 Ethicon employee that put the data together. 15 Q. Do you agree with those words? 16 A. Yes. 17 Q. Are those words from Ethicon's employee 18 who wrote this slide consistent with the opinions 19 you've been expressing throughout the last two 20 days? 21 A. Yes. 22 Q. Is there any other part of this exhibit 23 that you want to discuss with the ladies and 24 gentlemen of the jury?</p>	<p>1 talking about throughout the last two days? 2 A. Yes. 3 Q. And is this the interim data or the 4 12-month data? 5 A. The 12-month data. 6 Q. Okay. Now, before we get into this 7 document, did Ethicon ever publish to the medical 8 community the results from the 12-month First Human 9 Use Study? 10 A. No. 11 Q. And what opinions does the data from the 12 12-month First Human Use Study support? 13 A. This supports my opinions that there are 14 design characteristics that are defective in the 15 TVT-Secur device that makes it unreasonably unsafe 16 and also unreasonably ineffective. 17 Q. And how does it support those opinions? 18 A. The data shows a high failure rate in 19 the first 12 months and a high complication rate. 20 Q. This is kind of a pretty thick document, 21 but can you just walk us through it, the pages you 22 want to discuss with the jury. 23 MR. SNELL: Object. 24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 526	Page 528
<p>1 A. On page 7, it discusses what the 2 efficacy was for the trial. 3 BY MR. THORNBURGH: 4 Q. And what was the efficacy for this 5 study? 6 A. The main endpoint was a greater than 50% 7 change from baseline in visual analog scores for 8 incontinence. 9 And while they were greater -- only 89% 10 of patients with the U and 86% of the patients with 11 the H had a greater than 50% change in their 12 variables of incontinence. 13 Objective positive stress test was 14 positive in 17% of the U and 32% of the -- of the H. 15 Q. What does that mean? Just stop there 16 for a second. 17 A. That almost 20% of patients in the U and 18 over 30% of patients who had the H had positive 19 leakage. 20 Q. And what does that mean in terms of 21 efficacy? 22 A. That when added together, over 26% of 23 patients failed. 24 Q. Are those results good outcomes for</p>	<p>1 the report, unless you're not done. 2 A. No, I was going to the adverse events 3 section. There is a total of 51 adverse events 4 reported in 32 subjects during the 12-month study. 5 31% of subjects or 31% of the subjects considered 6 the adverse event to be related or possibly related 7 to the device. 8 There were close to 30% of patients that 9 had major device-related complications. 70% of 10 subjects had no major device-related complications, 11 meaning 30% of subjects had major device-related 12 complications. 13 Q. And does that -- what does that mean in 14 lay terms? 15 A. There's a significant number of adverse 16 events and a significant number of severe adverse 17 events. 18 Q. And how does that information support 19 your opinion, if at all? 20 A. This supports my opinion that there are 21 design characteristics of the TVT-Secur device that 22 make it unreasonably unsafe and unreasonably 23 ineffective in treating stress urinary 24 incontinence.</p>
Page 527	Page 529
<p>1 patients? 2 A. No. 3 Q. Did this study meet its primary endpoint 4 of or secondary endpoint of success or did it fail 5 its secondary endpoint for success? 6 A. Well, again -- 7 MR. SNELL: Object. 8 BY THE WITNESS: 9 A. I apologize. That was five-week data 10 that I just discussed. 11 The 12-month data is actually even -- 12 even worse. The improvement rate was 80% for the U 13 and 60% for the H, a greater than 50% improvement, 14 and the positive stress test was positive in 25% of 15 the U and 47% of the H. 16 BY MR. THORNBURGH: 17 Q. What was the failure rate? 18 A. Approximately 35% or higher. 19 Q. Did the efficacy for the TVT-Secur 20 device get better or worse since the interim data 21 was available to Ethicon back in September of 2006 22 before launch? 23 A. It got worse. 24 Q. And if you turn the page to page 8 of</p>	<p>1 Q. What's the next page you'd like to 2 discuss, Doctor? 3 A. It is P2691. 4 Q. If we can, real quick, just turn to 5 page 16 just briefly. 6 A. Of the previous document? 7 Q. No. Of the -- of Exhibit 934, P934. 8 A. Okay. 9 Q. Are you there? 10 A. Yes. 11 Q. And does this identify the surgeons who 12 participated in this research? 13 MR. SNELL: Object; leading. 14 BY THE WITNESS: 15 A. Yes. 16 BY MR. THORNBURGH: 17 Q. Who were the doctors that participated 18 in this study? 19 A. Dr. Nilsson, Dr. Artibani, Dr. Karram, 20 Dr. Lucente, Dr. Khandwala and Dr. Dmochowski. 21 Q. And we looked at a document earlier 22 regarding whether or not Dr. Nilsson and Artibani 23 had continued to support the TVT-Secur. Do you 24 recall that?</p>

45 (Pages 526 to 529)

Bruce Alan Rosenzweig, M.D.

Page 530	Page 532
<p>1 A. Yes.</p> <p>2 Q. Can you refresh the recollection for the</p> <p>3 jury what that issue was?</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. That Dr. Nilsson and Artibani could not</p> <p>7 support the TVT-Secur device because there were no</p> <p>8 randomized controlled trials.</p> <p>9 Q. And they were also the two of the</p> <p>10 investigators in the study, is that correct?</p> <p>11 MR. SNELL: Object; leading.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Correct.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. And are the -- based on your knowledge,</p> <p>16 training and experience, your review of the medical</p> <p>17 literature and your review of the internal Ethicon</p> <p>18 company documents, were these six surgeons</p> <p>19 considered to be experienced in the treatment of</p> <p>20 stress urinary incontinence?</p> <p>21 A. Yes.</p> <p>22 Q. And if you turn with me to page 80. And</p> <p>23 can you tell us what the first paragraph is stating</p> <p>24 in this exhibit?</p>	<p>1 paragraph, what does the next paragraph say?</p> <p>2 A. "There have been more reports of serious</p> <p>3 complications with the TVT-Secur device and the</p> <p>4 rates of minor complications seen in the study and</p> <p>5 in those by Meschia and Martan are not very much</p> <p>6 lower than the early reports of the TVT and TVT-O</p> <p>7 procedures."</p> <p>8 Q. And what does this statement --</p> <p>9 MR. SNELL: Object; misstates. Move to</p> <p>10 strike.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. What does this statement mean to you</p> <p>13 that there have been reports of more serious</p> <p>14 complications with the TVT-Secur devices?</p> <p>15 A. This shows the design characteristics of</p> <p>16 the TVT-Secur device that make it unreasonably</p> <p>17 unsafe and unreasonably ineffective.</p> <p>18 Q. And what's the next paragraph say?</p> <p>19 MR. SNELL: Object; reading.</p> <p>20 BY THE WITNESS:</p> <p>21 A. "In the future, well-planned randomized</p> <p>22 studies will have to be conducted in order to</p> <p>23 discern if a new single-incision procedure can</p> <p>24 achieve the same level of effectiveness as has been</p>
Page 531	Page 533
<p>1 MR. SNELL: Object; reading.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. On page 80.</p> <p>4 MR. SNELL: Sorry. Object, reading.</p> <p>5 BY THE WITNESS:</p> <p>6 A. This is describing the learning curve</p> <p>7 that we discussed before.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And isn't it correct that we looked at a</p> <p>10 document from David Robinson who -- that stated</p> <p>11 that he felt that the data from the First Human Use</p> <p>12 Study would get better after they enrolled more</p> <p>13 patients into the longer follow-up 12-month study?</p> <p>14 Do you recall that?</p> <p>15 MR. SNELL: Objection; leading.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Did the data get better?</p> <p>20 MR. SNELL: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. No.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Now, if you go down to the next</p>	<p>1 previously shown with the TVT procedure and (with</p> <p>2 shorter follow-up) also with the TVT-O procedure."</p> <p>3 MR. SNELL: Object. I'm sorry, Doctor.</p> <p>4 You've misspoke. Move to strike answer.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Go ahead and read it again just in case</p> <p>7 there was an error.</p> <p>8 A. "In the future, well-planned randomized</p> <p>9 studies will have to be conducted in order to</p> <p>10 discern if the new single-incision procedures can</p> <p>11 achieve the same level of effectiveness as has been</p> <p>12 extensively shown with the TVT procedure and (with</p> <p>13 shorter follow-up) also the TVT-O procedure."</p> <p>14 Q. Okay. And go ahead and continue on,</p> <p>15 Doctor.</p> <p>16 A. "Substantial effort has been channelled</p> <p>17 into developing a design of a single-incision sling</p> <p>18 that facilitates a safer and easier insertion. As</p> <p>19 long as complications occur at the rate seen in</p> <p>20 this study and invasiveness is not much lower than</p> <p>21 with traditional midurethra tension-free</p> <p>22 operations, the single-incision procedure cannot be</p> <p>23 recommended as a first-line treatment for stress</p> <p>24 urinary incontinence."</p>

46 (Pages 530 to 533)

Bruce Alan Rosenzweig, M.D.

Page 534	Page 536
<p>1 Q. Dr. Rosenzweig, how does this 2 information support your opinion? 3 MR. SNELL: Object; leading. 4 BY THE WITNESS: 5 A. This supports my opinion that the 6 TVT-Secur device was not adequately studied prior 7 to launch, that there are design characteristics 8 that make it unreasonably unsafe and make it 9 unreasonably in -- ineffective in treating stress 10 urinary incontinence. And the statement that it 11 cannot be used for first-line treatment for stress 12 urinary incontinence supports those opinions. 13 BY MR. THORNBURGH: 14 Q. And did Ethicon, to your knowledge, 15 based on your review of the internal documents, 16 ever disclose to physicians who were considering 17 treatment options to treat their patients who had 18 stress urinary incontinence that the TVT-Secur 19 could not be recommended for first-line treatment 20 of that condition? 21 A. No. 22 Q. Was it common knowledge based on your 23 review of the medical literature, your review of 24 the internal company documents and your knowledge,</p>	<p>1 Q. Do you have an opinion whether or not 2 patients did in fact suffer harm as a result of 3 Ethicon's failure to disclose this information? 4 MR. SNELL: Objection. 5 BY THE WITNESS: 6 A. Yes, I do have an opinion. 7 BY MR. THORNBURGH: 8 Q. And what's that opinion? 9 MR. SNELL: Same. 10 BY THE WITNESS: 11 A. Yes, they did suffer harm. 12 BY MR. THORNBURGH: 13 Q. And when it talks about the need for 14 randomized clinical controlled -- randomized 15 controlled trials in this -- on this page. Do you 16 see that? 17 A. Yes. 18 Q. Are those the studies that Ethicon had 19 initially committed to do prior to launching the 20 TVT-Secur device? 21 MR. SNELL: Objection. 22 BY THE WITNESS: 23 A. Yes. 24 BY MR. THORNBURGH:</p>
Page 535	Page 537
<p>1 training and experience that the TVT-Secur should 2 not be used as first-line therapy for the treatment 3 of stress urinary incontinence? 4 MR. SNELL: Objection. 5 BY THE WITNESS: 6 A. No, that was not common knowledge. 7 BY MR. THORNBURGH: 8 Q. Do you have an opinion as to whether or 9 not Ethicon should have disclosed the conclusions 10 from their own internal study concerning whether or 11 not the Secur should be used as a first-line 12 treatment option? 13 MR. SNELL: Objection. 14 BY THE WITNESS: 15 A. Yes. 16 BY MR. THORNBURGH: 17 Q. What's that opinion? 18 A. That it should have been disclosed. 19 Q. What happens if Ethicon doesn't disclose 20 information like this to patients? 21 MR. SNELL: Object. 22 BY THE WITNESS: 23 A. Patients can suffer harm. 24 BY MR. THORNBURGH:</p>	<p>1 Q. And what are Ethicon's Key Opinion 2 Leaders stating again about the need for randomized 3 controlled trials? 4 A. That there's a need for randomized 5 controlled trials. 6 Q. And do you agree with that? 7 A. Yes. 8 Q. If you had not been hired in this case 9 as an expert witness and had an opportunity to 10 review Ethicon's internal company documents, would 11 you have known about the results of this 12-month 12 First Human Use Study? 13 MR. SNELL: Objection. 14 BY THE WITNESS: 15 A. No. 16 BY MR. THORNBURGH: 17 Q. Would you have known that Ethicon's Key 18 Opinion Leaders who conducted this First Human Use 19 Study had concluded that the TVT-Secur had a higher 20 rate of complications than the other TVT products 21 that Ethicon had on the market at the time? 22 MR. SNELL: Objection. 23 BY THE WITNESS: 24 A. No.</p>

47 (Pages 534 to 537)

Bruce Alan Rosenzweig, M.D.

Page 538	Page 540
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Would you have known, had you not been</p> <p>3 asked to serve as an expert in this case and had</p> <p>4 access to Ethicon's internal documents, that</p> <p>5 Ethicon's Key Opinion Leaders had recommended</p> <p>6 against the use of the TVT-Secur device as</p> <p>7 first-line therapy for the treatment of stress</p> <p>8 urinary incontinence?</p> <p>9 MR. SNELL: Objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. No.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Is Ethicon's failure to provide this</p> <p>14 type of information to physicians who are</p> <p>15 considering which treatment options are appropriate</p> <p>16 for their patients the type of information that</p> <p>17 should be shared with doctors?</p> <p>18 A. Yes.</p> <p>19 Q. Is it the type of information that could</p> <p>20 be shared with doctors?</p> <p>21 A. Yes.</p> <p>22 Q. Is it the type of information that</p> <p>23 doctors consider in their risk/benefit assessment?</p> <p>24 MR. SNELL: Objection.</p>	<p>1 Q. And that their doctors were never made</p> <p>2 aware of what Ethicon knew internally, that the</p> <p>3 product should not be used as first-line therapy?</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Same for women in Florida?</p> <p>9 MR. SNELL: Same objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Same for women in California?</p> <p>14 MR. SNELL: Same.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Same for women in West Virginia?</p> <p>19 MR. SNELL: Same.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Yes.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. Is it appropriate for companies like</p> <p>24 Ethicon to withhold that type of information?</p>
Page 539	Page 541
<p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Is it the type of information that</p> <p>5 should be disclosed when Ethicon is promoting their</p> <p>6 products or giving the world an update on the good,</p> <p>7 the bad and the ugly?</p> <p>8 MR. SNELL: Object and leading.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Yes.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. So, doctors were implanting the Secur</p> <p>13 all across the country as first-line treatment for</p> <p>14 stress urinary incontinence because Ethicon didn't</p> <p>15 share with them what they knew internally?</p> <p>16 MR. SNELL: Objection, leading and lacks</p> <p>17 foundation.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Correct.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Is it fair to say that women in</p> <p>22 Pennsylvania continued to be implanted with the</p> <p>23 stress -- with the TVT-Secur?</p> <p>24 A. Yes.</p>	<p>1 MR. SNELL: Object.</p> <p>2 BY THE WITNESS:</p> <p>3 A. No.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. What happens to patients -- what can</p> <p>6 happen to patients if Ethicon withholds important</p> <p>7 information such as this that their own Key Opinion</p> <p>8 Leaders who performed this internal study felt that</p> <p>9 the TVT-Secur should not be used for -- as therapy</p> <p>10 for first -- first-line therapy for stress urinary</p> <p>11 incontinence?</p> <p>12 MR. SNELL: Objection; leading.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Patients can suffer harm.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And do you have an opinion as to whether</p> <p>17 or not patients did in fact suffer harm as a result</p> <p>18 of Ethicon's failure to disclose this information,</p> <p>19 that their Key Opinion Leaders felt that the</p> <p>20 TVT-Secur should not be used as first-line</p> <p>21 treatment for the treatment of stress urinary</p> <p>22 incontinence?</p> <p>23 MR. SNELL: Objection; leading.</p> <p>24 BY THE WITNESS:</p>

48 (Pages 538 to 541)

Bruce Alan Rosenzweig, M.D.

Page 542	Page 544
<p>1 A. Yes, I have an opinion.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. What's that opinion?</p> <p>4 MR. SNELL: Same.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes, they did suffer harm.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. What types of harm were women suffering?</p> <p>9 MR. SNELL: Same.</p> <p>10 BY THE WITNESS:</p> <p>11 A. The complications that I've described</p> <p>12 previously, pain, pain with intercourse, mesh</p> <p>13 erosion, voiding problems, irritative voiding</p> <p>14 symptoms, erosion into the vagina, erosion into the</p> <p>15 urethra, erosion into the bladder, among others.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. What's the next document in your binder</p> <p>18 that you'd like to discuss with -- strike that.</p> <p>19 What's the next tab number that you'd</p> <p>20 like to discuss with the jury?</p> <p>21 A. P2691.</p> <p>22 Q. Exhibit 2691?</p> <p>23 A. Yes.</p> <p>24 Q. What's the tab number in your binder?</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Is this the first time we've heard</p> <p>3 criticisms or seen criticisms being discussed in</p> <p>4 Ethicon's own documents about its decision to</p> <p>5 launch the TVT-Secur without having complete data?</p> <p>6 MR. SNELL: Object.</p> <p>7 BY THE WITNESS:</p> <p>8 A. No.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Is this the first time that we've seen</p> <p>11 the company discuss the possibility of publications</p> <p>12 being written criticizing Ethicon for their</p> <p>13 unethical behavior in launching the TVT-Secur</p> <p>14 product?</p> <p>15 MR. SNELL: Object.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And if you go on the first page to the</p> <p>20 first e-mail from Mark Yale, what does that e-mail</p> <p>21 say and who was it addressed to?</p> <p>22 A. It is from Mark Yale to Lesley Fronio</p> <p>23 stating that "It seems that Danish marketing has</p> <p>24 contacted Piet Hinoul about a physician (who worked</p>
Page 543	Page 545
<p>1 A. 50.</p> <p>2 Q. Okay. And can you identify this exhibit</p> <p>3 for the ladies and gentlemen of the jury, please?</p> <p>4 A. Yes, this is an e-mail string between</p> <p>5 Mark Yale and Bryan Lisa, key Ethicon employees,</p> <p>6 dated December 14, 2009.</p> <p>7 Q. And what opinions does Exhibit 2691</p> <p>8 support?</p> <p>9 A. That the TVT-Secur was not adequately</p> <p>10 studied prior to launch.</p> <p>11 Q. And how does it support that opinion?</p> <p>12 A. This is an e-mail from Lesley Fronio to</p> <p>13 Mark Yale, both key Ethicon employees, regarding an</p> <p>14 article being published in a Danish -- in a Danish</p> <p>15 publication from the experience of a physician who</p> <p>16 felt it was unethical behavior on the part of</p> <p>17 Ethicon to release the TVT-Secur without clinical</p> <p>18 data.</p> <p>19 Q. Is this --</p> <p>20 MR. SNELL: Object. I'm sorry.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Is this the first time --</p> <p>23 MR. SNELL: Object. Move to strike. Reading.</p> <p>24 Go ahead.</p>	<p>1 with Contoura) writing an article to be published</p> <p>2 tomorrow about unethical behavior in releasing the</p> <p>3 TVT-Secur without clinical data."</p> <p>4 MR. SNELL: Move to strike. Reading.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. How does Lesley Fronio respond to Mark?</p> <p>7 MR. SNELL: Same objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. "I'm on the phone with Zeb. Here's the</p> <p>10 deal: There is a surgeon who is upset with all</p> <p>11 companies who put foreign material in the body,</p> <p>12 specifically around the midurethral segment. He</p> <p>13 believes the TVT-Secur" --</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Sorry. I just want to back up. I think</p> <p>16 you read that wrong. It says, "Mini-sling</p> <p>17 segment."</p> <p>18 A. Mini-sling segment.</p> <p>19 Q. Go ahead. Read that again, Doctor.</p> <p>20 A. "There is a surgeon who" -- "who upset</p> <p>21 with all companies who put foreign material in the</p> <p>22 body, specifically around the mini-sling segment.</p> <p>23 He believes that the TVT-S was launched without</p> <p>24 data so he is upset and is using this as an example</p>

49 (Pages 542 to 545)

Bruce Alan Rosenzweig, M.D.

Page 546	Page 548
<p>1 to highlight all companies, not just ours."</p> <p>2 Q. And what did Ethicon do when they</p> <p>3 learned about this additional publication that</p> <p>4 might come out concerning the behavior or the</p> <p>5 decision to launch the TVT-Secur without conducting</p> <p>6 adequate studies?</p> <p>7 MR. SNELL: Object; form. I'm sorry. Not</p> <p>8 form. Objection.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Nothing that I recall from reviewing the</p> <p>11 internal documents.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And how did they -- what's the next</p> <p>14 document you'd like to discuss with the ladies and</p> <p>15 gentlemen of the jury?</p> <p>16 MR. SNELL: While the doctor is looking, I'll</p> <p>17 just note P2691, objection as to foreign regulatory</p> <p>18 concerning Danish regulator EUCOMED and FDA. Go</p> <p>19 ahead.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Go ahead, Doctor.</p> <p>22 A. It is an e-mail string including Judi</p> <p>23 Gauld, Jacqueline Russo and David Robinson.</p> <p>24 Q. And what opinions does Exhibit 2685</p>	<p>1 A. Yes.</p> <p>2 Q. Okay. And what does -- remember we</p> <p>3 actually talked about Jacqueline Russo-Jankewicz</p> <p>4 earlier, didn't we?</p> <p>5 A. Yes.</p> <p>6 Q. Was that in relation -- I can't</p> <p>7 remember. Was that with respect to the year prior</p> <p>8 where Ethicon had drafted a different media</p> <p>9 statement to respond to similar articles being</p> <p>10 published?</p> <p>11 MR. SNELL: Objection.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Now, what does Ms. Russo-Jankewicz write</p> <p>16 to Aaron Kirkemo -- to Aaron and to Piet?</p> <p>17 MR. SNELL: Object.</p> <p>18 BY THE WITNESS:</p> <p>19 A. "There was an unfavorable news story</p> <p>20 about mini-slugs on Danish television.</p> <p>21 TVT-Secur/J&J was referenced even though we do not</p> <p>22 market Secur in Denmark or Scandinavia. The</p> <p>23 commercial team there has requested a standby in</p> <p>24 case we receive inquiries from the press."</p>
Page 547	Page 549
<p>1 support?</p> <p>2 A. My opinions of that Ethicon failed to</p> <p>3 adequately study the TVT-Secur device before</p> <p>4 launch.</p> <p>5 Q. And how does this document support that</p> <p>6 opinion?</p> <p>7 A. There's an e-mail from Dr. Robinson to</p> <p>8 Judi Gauld, "Did the human trial actually precede</p> <p>9 launch or was it post-launch" -- "or was it</p> <p>10 post-approval pre-launch?"</p> <p>11 Then Judi writes to Jackie, "Just to</p> <p>12 confirm that we conducted a post-CE mark /</p> <p>13 post-510(k) clearance study with Secur. By the</p> <p>14 time of launch we had five-week interim data on 31</p> <p>15 patients."</p> <p>16 Q. Okay. Does this e-mail --</p> <p>17 MR. SNELL: Object.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. -- also relate to that Danish article</p> <p>20 that Ethicon had discussed in their last -- the</p> <p>21 last exhibit we looked at?</p> <p>22 A. Yes.</p> <p>23 Q. And if you turn to page Bates number</p> <p>24 ending in 5998. Are you there?</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Okay. Now, if you go again -- is this</p> <p>3 similar to what we saw a year prior?</p> <p>4 MR. SNELL: Objection.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Yes.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And what does the second bullet point</p> <p>9 say?</p> <p>10 A. "Prior to making TVT-Secur commercially</p> <p>11 available, Ethicon validated the safety of the</p> <p>12 device in a clinical protocol (humans) in six sites</p> <p>13 in Europe and the United States."</p> <p>14 Q. Is that a correct statement?</p> <p>15 A. No.</p> <p>16 Q. Did the interim data from the First</p> <p>17 Human Use Study validate the safety of the</p> <p>18 TVT-Secur product?</p> <p>19 MR. SNELL: Object.</p> <p>20 BY THE WITNESS:</p> <p>21 A. No.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. And did the 12-month data that was</p> <p>24 eventually published in 2000 -- not published. Did</p>

Bruce Alan Rosenzweig, M.D.

Page 550	Page 552
<p>1 the 12 -- strike that.</p> <p>2 Did the 12-month data from the First</p> <p>3 Human Use Study validate the safety or efficacy of</p> <p>4 the TVT-Secur product?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. No.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Was this an opportunity for Ethicon to</p> <p>10 tell the media that they released the TVT-Secur</p> <p>11 product without validating the safety or efficacy</p> <p>12 of the product before they launched it?</p> <p>13 MR. SNELL: Object.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yes.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Did they disclose that information?</p> <p>18 MR. SNELL: Same.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Could they have?</p> <p>23 A. Yes.</p> <p>24 Q. Should they have?</p>	<p>1 question, "Did the human trial actually precede</p> <p>2 launch?"</p> <p>3 Do you see that?</p> <p>4 A. Yes.</p> <p>5 MR. SNELL: Object. Go ahead.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. This is the guy that looked at the</p> <p>8 interim data, right?</p> <p>9 MR. SNELL: Object; leading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. This is the guy that actually let the</p> <p>14 product be launched on to the -- into the market?</p> <p>15 MR. SNELL: Object; leading.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. After he looked at that data?</p> <p>18 MR. SNELL: Same.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Yes.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Yet he's asking other people at Ethicon</p> <p>23 whether or not the human study was done before or</p> <p>24 after the product had been launched?</p>
Page 551	Page 553
<p>1 MR. SNELL: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. If you turn to page -- the next page in</p> <p>6 P2685, there was a statement that you had discussed</p> <p>7 a moment ago from Dr. David Robinson.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. And we know -- we have talked about</p> <p>11 Dr. Robinson yesterday and throughout today. But</p> <p>12 just briefly remind the jury who he is and what</p> <p>13 responsibility he had with respect to the launch of</p> <p>14 the TVT-Secur product?</p> <p>15 MR. SNELL: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. He was medical director.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Okay. And is Dr. David Robinson the</p> <p>20 Medical Affairs director at Ethicon who actually</p> <p>21 analyzed the TVT-Secur interim data from the First</p> <p>22 Human Use Trial before launch?</p> <p>23 A. Yes.</p> <p>24 Q. And Dr. Robinson writes to Judi with a</p>	<p>1 MR. SNELL: Object; leading.</p> <p>2 BY THE WITNESS:</p> <p>3 A. That's what the e-mail states.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Do you have an opinion whether or not</p> <p>6 Ethicon's conduct was appropriate in launching the</p> <p>7 TVT-Secur product based on the data they had</p> <p>8 available to them in 2006?</p> <p>9 MR. SNELL: Objection.</p> <p>10 BY THE WITNESS:</p> <p>11 A. I do not feel that the TVT-Secur should</p> <p>12 have been launched with the data that was available</p> <p>13 in 2006.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. What's the next document in your tab,</p> <p>16 Doctor?</p> <p>17 A. P2719.</p> <p>18 Q. And can you identify what P2719 is?</p> <p>19 A. It is a standby media statement from</p> <p>20 December 16, 2009.</p> <p>21 MR. THORNBURGH: Tom, can you put side by side</p> <p>22 the clinical study report, Exhibit 0934, which is</p> <p>23 the report concerning the 12-month First Human Use</p> <p>24 data.</p>

51 (Pages 550 to 553)

Bruce Alan Rosenzweig, M.D.

Page 554	Page 556
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Now, Doctor, what was the date on the</p> <p>3 draft report concerning the 12-month First Human</p> <p>4 Use data?</p> <p>5 A. July of 2009.</p> <p>6 Q. And what is the date of the standby</p> <p>7 statement?</p> <p>8 A. December of 2009.</p> <p>9 Q. Is it accurate, then, that Ethicon</p> <p>10 actually had the data from the -- in a first draft</p> <p>11 from the 12-month First Human Use Study prior to</p> <p>12 writing this standby statement?</p> <p>13 MR. SNELL: Object.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yes.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And by just a couple months in fact, is</p> <p>18 that correct?</p> <p>19 MR. SNELL: Leading. Object.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Yes.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. And did Ethicon disclose in their</p> <p>24 standby media statement that the 12-month data was</p>	<p>1 standby statement.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And was it?</p> <p>4 A. No.</p> <p>5 MR. SNELL: Same.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And if you look at Exhibit 2719, what</p> <p>8 data does Ethicon discuss would be published -- was</p> <p>9 recently published?</p> <p>10 A. The data from the TVT registry.</p> <p>11 Q. Is that the TVT-WORLD?</p> <p>12 A. Yes.</p> <p>13 Q. And is that the same study that we have</p> <p>14 looked at earlier or the e-mails that related to</p> <p>15 those studies that we looked at earlier that</p> <p>16 discussed an employee by the name of Derringer or</p> <p>17 Dhinagar?</p> <p>18 A. Yes.</p> <p>19 MR. SNELL: Objection; leading.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. And what were -- and can you remind the</p> <p>22 jury again what the issues were with respect to</p> <p>23 Dhinagar and the TVT-WORLD interim analysis and</p> <p>24 publication?</p>
Page 555	Page 557
<p>1 available?</p> <p>2 MR. SNELL: Objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Did Ethicon disclose in the standby</p> <p>7 statement that the First Human Use data from the</p> <p>8 12-month follow-up study demonstrated a lack of</p> <p>9 efficacy and safety concerns?</p> <p>10 MR. SNELL: Objection; foundation.</p> <p>11 BY THE WITNESS:</p> <p>12 A. That is not -- that is not in this</p> <p>13 document.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Did Ethicon have an opportunity in the</p> <p>16 standby statement of December 16 of 2009 to tell</p> <p>17 the world that after reviewing the results from the</p> <p>18 12-month First Human Use Study that it was</p> <p>19 Ethicon's Key Opinion Leaders' conclusions that the</p> <p>20 TVT-Secur should not be used for first-line therapy</p> <p>21 to treat stress urinary incontinence?</p> <p>22 MR. SNELL: Objection.</p> <p>23 BY THE WITNESS:</p> <p>24 A. That could have been included in this</p>	<p>1 MR. SNELL: Objection and leading now.</p> <p>2 BY THE WITNESS:</p> <p>3 A. That there were adverse events that were</p> <p>4 potentially or were mischaracterizing that they</p> <p>5 wanted to spin the data.</p> <p>6 MR. SNELL: Note my objection. P2719,</p> <p>7 Ethicon.MESH ending in 595165 not on reliance list.</p> <p>8 Move to strike all questions about it.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. What's the next tab in your binder that</p> <p>11 you want to discuss?</p> <p>12 A. P2684.</p> <p>13 Q. What's the tab number, Doctor?</p> <p>14 A. Oh. 53.</p> <p>15 Q. And Exhibit -- did you say 2684?</p> <p>16 A. P2684.</p> <p>17 Q. Okay. And can you identify Exhibit 2684</p> <p>18 for the ladies and gentlemen of the jury?</p> <p>19 A. It is an e-mail string between key</p> <p>20 Ethicon employees from March 10, 2010, including</p> <p>21 Dan Smith, project leader and co-inventor of the</p> <p>22 TVT-Secur, Aaron Kirkemo, Medical Director.</p> <p>23 Q. And what opinions does Exhibit 2684</p> <p>24 support?</p>

52 (Pages 554 to 557)

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 558</p> <p>1 A. That there was a failure to adequately</p> <p>2 study the TVT-Secur before launch.</p> <p>3 Q. And how does this exhibit support that</p> <p>4 opinion, Doctor? And you can walk us through the</p> <p>5 document if you want.</p> <p>6 MR. SNELL: Objection.</p> <p>7 BY THE WITNESS:</p> <p>8 A. It is -- part of the e-mail string is</p> <p>9 from Ethicon employee Alyson Wess to other Ethicon</p> <p>10 employees, including Dan Smith.</p> <p>11 It states, "I would send you a note to</p> <p>12 let you know that the marketing team has landed on</p> <p>13 a commercial call for our product launch. We want</p> <p>14 to continue to pursue the Scion PA project</p> <p>15 vigorously and do not wish to pursue the Scion PP</p> <p>16 version. TVT-Secur is weak and clearly not</p> <p>17 competitive with the MiniArc or the Solyx."</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Let's talk about this a little bit.</p> <p>20 First off, what is --</p> <p>21 MR. SNELL: Object and move to strike.</p> <p>22 Non-responsive.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Do you have an understanding what -- let</p>	<p style="text-align: right;">Page 560</p> <p>1 Ultrapro, a partially absorbable material?</p> <p>2 MR. SNELL: Object; leading.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Correct.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Now, and how did Alyson Wess</p> <p>7 characterize the TVT-Secur in this e-mail to her</p> <p>8 colleagues?</p> <p>9 MR. SNELL: Object; reading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. "If TVT is dead and we will not play in</p> <p>12 the single-incision sling space for four more years</p> <p>13 assuming we have good data, how can we throw</p> <p>14 dollars and shares into playing in two of the three</p> <p>15 sandboxes? I hear what they think via AW e-mail."</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. I just want to stop you real quick</p> <p>18 because that's Dan Smith, but before we get to</p> <p>19 Dan Smith's response, how did Alyson Wess or Wess</p> <p>20 characterize the TVT-Secur?</p> <p>21 MR. SNELL: Move to strike the prior answer as</p> <p>22 non-responsive to the question.</p> <p>23 BY THE WITNESS:</p> <p>24 A. It is "weak and clearly not</p>
<p style="text-align: right;">Page 559</p> <p>1 me start again because I think there was -- we were</p> <p>2 talking over each other.</p> <p>3 What is Scion PA?</p> <p>4 A. It is a project to make a new generation</p> <p>5 sling that is partially absorbable.</p> <p>6 Q. Partially, did you say partially</p> <p>7 absorbable?</p> <p>8 A. Yes.</p> <p>9 Q. What was Scion PP?</p> <p>10 A. It is also another pelvic floor product</p> <p>11 that was complete -- completely made of</p> <p>12 polypropylene.</p> <p>13 Q. Now, you've testified previously about</p> <p>14 some partially absorbable materials that Ethicon</p> <p>15 had available to them, is that correct?</p> <p>16 MR. SNELL: Object; leading.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Correct.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. And you've talked about the Ultrapro in</p> <p>21 your prior testimony?</p> <p>22 A. Correct.</p> <p>23 Q. Now, I understand that the Scion PA</p> <p>24 isn't exactly Ultrapro, but it is also, like</p>	<p style="text-align: right;">Page 561</p> <p>1 competitive."</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And are those your words, Doctor?</p> <p>4 MR. SNELL: Object.</p> <p>5 BY THE WITNESS:</p> <p>6 A. No.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Do you agree with those words?</p> <p>9 A. Yes.</p> <p>10 Q. And when is Alyson Wess writing to her</p> <p>11 colleagues where she's categorizing the TVT-Secur</p> <p>12 as weak?</p> <p>13 A. March of 2010.</p> <p>14 Q. Now, how did Dan Smith respond to Alyson</p> <p>15 Wess?</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. "If TVT-Secur is dead and we will not</p> <p>19 play in the single-incision sling space for four</p> <p>20 more years assuming we get good data, how can we</p> <p>21 grow dollars and shares by only playing in two of</p> <p>22 three sandboxes?"</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. What's your interpretation of that,</p>

Bruce Alan Rosenzweig, M.D.

Page 562	Page 564
<p>1 Doctor?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. That Dan Smith is acknowledging that the</p> <p>5 TVT-Secur is a failed product.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Do you agree with that based on your</p> <p>8 review of the internal documents and the published</p> <p>9 peer-reviewed articles?</p> <p>10 MR. SNELL: Objection; misstates as well.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And what else does Dan Smith say?</p> <p>15 MR. SNELL: Same objection. Reading now.</p> <p>16 BY THE WITNESS:</p> <p>17 A. "I hear what they think via AW e-mail</p> <p>18 but what if Abbrevio can't play in the single</p> <p>19 incision sandbox because it is simply not a</p> <p>20 single-incision sling? Per my earlier e-mail, it</p> <p>21 is hard to see why needing one-year data would add</p> <p>22 much more to the year and a half" -- "more than a</p> <p>23 year and a half to the timeline, and if we truly</p> <p>24 think six months is appropriate, which I think we</p>	<p>1 MR. SNELL: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. That Dan Smith is implying that they</p> <p>4 only need six months of data to launch the product</p> <p>5 instead of one year of data.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Now, we saw in the interview with</p> <p>8 Dr. Nilsson what Dr. Nilsson felt about short-term</p> <p>9 data, didn't we?</p> <p>10 MR. SNELL: Object and leading.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Can you remind the jury what Dr. Nilsson</p> <p>15 had stated concerning this type of data?</p> <p>16 MR. SNELL: Same objections.</p> <p>17 BY THE WITNESS:</p> <p>18 A. He stated that doctors and surgeons are</p> <p>19 allergic to six-week and six-month data.</p> <p>20 MR. THORNBURGH: Now, if Tom can go ahead and</p> <p>21 pull upside by side with this document</p> <p>22 Exhibit P0706 and pull up the "Lessons Learned"</p> <p>23 slide.</p> <p>24 BY MR. THORNBURGH:</p>
Page 563	Page 565
<p>1 do, then we are talking about adding a year."</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Now, let's break this down a little real</p> <p>4 quick.</p> <p>5 What are the three sandboxes that Dr. --</p> <p>6 that Dan Smith, Mr. Smith, is referring to here in</p> <p>7 this e-mail?</p> <p>8 A. The three different categories of</p> <p>9 products, the retropubic sling, the obturator sling</p> <p>10 and the single-incision sling.</p> <p>11 Q. And what concerns is Dan Smith relaying</p> <p>12 about the possibility that the TVT-Secur is dead?</p> <p>13 MR. SNELL: Objection.</p> <p>14 BY THE WITNESS:</p> <p>15 A. That they will not have a sling in or a</p> <p>16 product in the mini-sling category.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And what's your understanding of the</p> <p>19 statement by Mr. Smith that "As per my earlier</p> <p>20 e-mail, it is hard to see why needing one year of</p> <p>21 data would add much more than 1.5 years to the</p> <p>22 timeline, and if we truly think six months is</p> <p>23 appropriate, which I think we do, then we are</p> <p>24 talking adding a year"?</p>	<p>1 Q. While he is doing that, Doctor, at this</p> <p>2 time in 2010 when they are talking about how</p> <p>3 TVT-Secur is weak and how the TVT-Secur is dead,</p> <p>4 did they continue to sell the TVT-Secur to</p> <p>5 patients?</p> <p>6 A. Yes.</p> <p>7 MR. SNELL: Objection.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. At this time when they're referring to</p> <p>10 the TVT-Secur as weak or as dead, are they</p> <p>11 continuing to promote the TVT-Secur as safe and</p> <p>12 effective to physicians?</p> <p>13 A. Yes.</p> <p>14 Q. Do you have an opinion whether or not</p> <p>15 that was appropriate?</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes, I have an opinion.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Now, did Ethicon ever learn its lessons?</p> <p>21 What's that opinion? I'm sorry.</p> <p>22 MR. SNELL: Same objection. Go ahead.</p> <p>23 BY THE WITNESS:</p> <p>24 A. That was not appropriate.</p>

Bruce Alan Rosenzweig, M.D.

Page 566	Page 568
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Did -- we talked about this document</p> <p>3 from 2007, "Lessons Learned." Does it appear to</p> <p>4 you that Ethicon ever learned its lesson?</p> <p>5 MR. SNELL: Objection and leading.</p> <p>6 BY THE WITNESS:</p> <p>7 A. No.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Why not?</p> <p>10 MR. SNELL: Same objection, speculation.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Or how so I should say?</p> <p>13 MR. SNELL: Same.</p> <p>14 BY THE WITNESS:</p> <p>15 A. They're discussing in this e-mail that</p> <p>16 they would only need six months' worth of data in</p> <p>17 order to launch a new product.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Is it appropriate for a company like</p> <p>20 Ethicon to continue or attempt to continue to keep</p> <p>21 the TVT-Secur on the market so that it could</p> <p>22 continue to earn money or protect its market share</p> <p>23 by having a product within this third sandbox?</p> <p>24 MR. SNELL: Objection and leading.</p>	<p>1 learning curve that are consistently placed and</p> <p>2 that have an efficacy that would be similar to the</p> <p>3 TVT.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Did the TVT-Secur have a short learning</p> <p>6 curve?</p> <p>7 A. No.</p> <p>8 Q. Did the TVT-Secur have -- was it able to</p> <p>9 be implanted consistently?</p> <p>10 A. No.</p> <p>11 Q. Was the TVT-Secur equally as effective</p> <p>12 as the TVT or TVT-O?</p> <p>13 A. No.</p> <p>14 Q. Now, Dan Smith sends another e-mail</p> <p>15 at -- on March 10, 2010 at it looks like -- I can't</p> <p>16 tell what time that is on my copy.</p> <p>17 What does Dan Smith say regarding how to</p> <p>18 treat this sensitive information?</p> <p>19 MR. SNELL: Objection; reading.</p> <p>20 BY THE WITNESS:</p> <p>21 A. "Please do not forward this (actually</p> <p>22 delete it please)."</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. I guess somebody forgot to delete his</p>
Page 567	Page 569
<p>1 BY THE WITNESS:</p> <p>2 A. I don't understand the question.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Is it -- strike that. I'll withdraw the</p> <p>5 question.</p> <p>6 Now, if you go down a little bit</p> <p>7 further, do you see where it says, "As you know,</p> <p>8 Scion retropubic was originally part of the Scion</p> <p>9 project. I separated it because of the difficulty</p> <p>10 of consistent placement due to very limited tissue</p> <p>11 in that area."</p> <p>12 What's that next sentence say?</p> <p>13 MR. SNELL: Object; reading.</p> <p>14 BY THE WITNESS:</p> <p>15 A. "This is a risky play given the market</p> <p>16 requirements of short learning curve, consistent</p> <p>17 placement and equal effectiveness to TVT."</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. What's your understanding of that</p> <p>20 statement?</p> <p>21 MR. SNELL: Same.</p> <p>22 BY THE WITNESS:</p> <p>23 A. That doctors who are using medical</p> <p>24 devices are more favorable to devices with a short</p>	<p>1 e-mail, huh?</p> <p>2 MR. SNELL: Objection; leading, argumentative.</p> <p>3 BY THE WITNESS:</p> <p>4 A. I'm reading the e-mail, so I don't know</p> <p>5 if it was ever deleted.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And is there anything further that you</p> <p>8 want to discuss regarding Dan Smith's e-mails in</p> <p>9 Exhibit 2684?</p> <p>10 A. No.</p> <p>11 MR. SNELL: Take a break and use the restroom.</p> <p>12 MR. THORNBURGH: Yes.</p> <p>13 THE VIDEOGRAPHER: Okay. The time is 2:33</p> <p>14 p.m. and we're going off the video record.</p> <p>15 (WHEREUPON, a recess was had</p> <p>16 from 2:33 to 2:40 p.m.)</p> <p>17 THE VIDEOGRAPHER: The time is 2:40 p.m. and</p> <p>18 we're back on the video record.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Doctor, what's the next exhibit you want</p> <p>21 to discuss?</p> <p>22 A. P1460.</p> <p>23 Q. And can you identify P1460 to the jury?</p> <p>24 A. Yes. It is an e-mail from Dan Smith</p>

55 (Pages 566 to 569)

Bruce Alan Rosenzweig, M.D.

Page 570	Page 572
<p>1 dated March 19, 2010.</p> <p>2 Q. And what opinion does this exhibit</p> <p>3 support?</p> <p>4 A. That the TVT-Secur device was a failed</p> <p>5 product, had design characteristics that were</p> <p>6 unreasonably unsafe and unreasonably ineffective in</p> <p>7 treating stress urinary incontinence.</p> <p>8 Q. And how does this document support that</p> <p>9 opinion?</p> <p>10 A. Dan Smith writes that the TVT-Secur</p> <p>11 obturator only version could have been improved in</p> <p>12 2008, but the TVT-Secur was considered a failure</p> <p>13 and did not warrant line extensions.</p> <p>14 Q. So, according to Dan Smith when was the</p> <p>15 TVT-Secur considered a failure?</p> <p>16 MR. SNELL: I'm sorry. I have to object as</p> <p>17 non-responsive to the last answer. Go ahead. Also</p> <p>18 regulatory. Apologies, Doctor.</p> <p>19 BY THE WITNESS:</p> <p>20 A. In 2008.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. So, and what's the date of this e-mail?</p> <p>23 A. March 19, 2010.</p> <p>24 Q. So, Ethicon, is it fair -- what did</p>	<p>1 the polypropylene version of the Scion?</p> <p>2 MR. SNELL: Object; leading.</p> <p>3 BY THE WITNESS:</p> <p>4 A. To my best understanding, yes.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. And do you see at the bottom of the</p> <p>7 page, the first page of Exhibit 1460, what does</p> <p>8 Dan Smith write to David and Paul?</p> <p>9 MR. SNELL: Object; reading.</p> <p>10 BY THE WITNESS:</p> <p>11 A. "Recently you just asked what could</p> <p>12 increase speed to market. What is frustrating to</p> <p>13 me is that this project has been around long enough</p> <p>14 to see three to five generations of top management</p> <p>15 leadership, each bringing new ideas into play."</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Stop right there for a second.</p> <p>18 When Dan Smith writes, "Recently you</p> <p>19 asked what could increase speed to market," does it</p> <p>20 appear to you whether or not Dan Smith had learned</p> <p>21 his lesson about rushing products to market?</p> <p>22 MR. SNELL: Objection and leading.</p> <p>23 BY THE WITNESS:</p> <p>24 A. This is describing increasing speed to</p>
Page 571	Page 573
<p>1 Ethicon do, if anything, after it determined in</p> <p>2 2008 that the TVT-Secur was a failed product?</p> <p>3 MR. SNELL: Object.</p> <p>4 BY THE WITNESS:</p> <p>5 A. They continued to commercialize the</p> <p>6 product until 2012.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. Do you have an opinion about whether or</p> <p>9 not Ethicon's decision to continue to sell the</p> <p>10 product, despite its determination that the</p> <p>11 TVT-Secur was a failed product for four more years,</p> <p>12 was appropriate or inappropriate?</p> <p>13 MR. SNELL: Objection.</p> <p>14 BY THE WITNESS:</p> <p>15 A. It would not be appropriate to continue</p> <p>16 to sell a product that was deemed a failure.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Now, if you -- what is this e-mail with</p> <p>19 Dan Smith and his colleagues regarding?</p> <p>20 A. Information regarding the Scion project.</p> <p>21 Q. Okay. And was this a follow-up</p> <p>22 discussion from that last e-mail that we looked at</p> <p>23 concerning whether or not to move forward with the</p> <p>24 partially absorbable version of the Scion versus</p>	<p>1 market. We've seen one of the lessons learned from</p> <p>2 a prior PowerPoint presentation about consequences</p> <p>3 of rushing products to market. So, even after that</p> <p>4 PowerPoint they're still discussing increasing</p> <p>5 speed to market.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. All right. What's the next document you</p> <p>8 want to discuss?</p> <p>9 Hold on one second, actually.</p> <p>10 Let me just do -- let's talk about</p> <p>11 one -- I skipped a document earlier. I think this</p> <p>12 could be the last document we discuss, internal</p> <p>13 document.</p> <p>14 A. Okay.</p> <p>15 Q. Let me hand you what I've marked as</p> <p>16 Exhibit P0241. This is the document that -- I</p> <p>17 didn't have a copy of it earlier. You had a copy</p> <p>18 of it earlier, though. I think it was maybe tab 35</p> <p>19 or --</p> <p>20 MR. THORNBURGH: Can you tell us, Raquel.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Okay.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Find it?</p>

56 (Pages 570 to 573)

Bruce Alan Rosenzweig, M.D.

Page 574	Page 576
<p>1 A. No. But --</p> <p>2 Q. I need to get a copy.</p> <p>3 MR. BRADFORD: 43.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. This is a little bit out of the</p> <p>6 chronological order, but what's the date of</p> <p>7 Exhibit P0241?</p> <p>8 A. February 9, 2009.</p> <p>9 Q. And can you identify what this document</p> <p>10 is?</p> <p>11 A. It's an e-mail from Aaron Kirkemo,</p> <p>12 Medical Director, to key Ethicon employees,</p> <p>13 including Harel Gadot in marketing.</p> <p>14 Q. And what opinion does this exhibit</p> <p>15 support?</p> <p>16 A. That there were design characteristics</p> <p>17 associated with the TVT-Secur device that made it</p> <p>18 unreasonably unsafe.</p> <p>19 Q. How does Exhibit P0241 support that</p> <p>20 opinion?</p> <p>21 A. Discusses the high complication rate</p> <p>22 associated with the TVT-Secur.</p> <p>23 Q. And if you go to the last bullet or last</p> <p>24 paragraph of the first page, you see where it</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And do you have an opinion whether or</p> <p>3 not the high complication rate and lack of efficacy</p> <p>4 made the TVT-Secur a failed product?</p> <p>5 MR. SNELL: Object.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Correct.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And are they talking about their concern</p> <p>10 here that patients might get hurt or are they more</p> <p>11 worried about their brand?</p> <p>12 MR. SNELL: Object; leading.</p> <p>13 BY THE WITNESS:</p> <p>14 A. It states that they're concerned about</p> <p>15 their brand.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And are these doctors in Australia or</p> <p>18 are these doctors in the United States?</p> <p>19 A. Dr. Kirkemo is Associate Medical</p> <p>20 Director worldwide in Somerville, New Jersey.</p> <p>21 Q. Does it appear that all of these people</p> <p>22 are U.S. employees of Ethicon?</p> <p>23 MR. SNELL: Object; leading.</p> <p>24 BY THE WITNESS:</p>
Page 575	Page 577
<p>1 says -- what does Aaron Kirkemo write concerning --</p> <p>2 in that last sentence of that last paragraph?</p> <p>3 MR. SNELL: Object; reading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. "As a consequence of these observations,</p> <p>6 many worried that the risk/benefit ratio could</p> <p>7 produce a backlash against pelvic floor mesh that</p> <p>8 would damage the entire pelvic floor platform.</p> <p>9 They said that they were concerned that should</p> <p>10 Prosima not work or have a high complication rate</p> <p>11 it could damage the EWHU brand just a TVT-Secur</p> <p>12 did."</p> <p>13 Q. Is that maybe a typo, "just as" --</p> <p>14 A. "As," yes.</p> <p>15 Q. -- "TVT-Secur did"?</p> <p>16 MR. SNELL: Leading.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. Does this indicate to you that Aaron</p> <p>19 Kirkemo was writing to his colleagues suggesting</p> <p>20 that the TVT-Secur had a high complication rate and</p> <p>21 did not work?</p> <p>22 MR. SNELL: Object.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Correct.</p>	<p>1 A. Correct.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And is it more important that companies</p> <p>4 make business decisions based on whether or not a</p> <p>5 product will help or hurt patients rather than</p> <p>6 whether or not the company's reputation could be</p> <p>7 harmed?</p> <p>8 MR. SNELL: Objection.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Patient safety should be paramount.</p> <p>11 MR. THORNBURGH: We are going to switch gears</p> <p>12 here. If we can just take a quick break. Let me</p> <p>13 just get my folders together.</p> <p>14 THE VIDEOGRAPHER: Okay. The time is 2:51</p> <p>15 p.m. and we're going off the video record.</p> <p>16 (WHEREUPON, a recess was had</p> <p>17 from 2:51 to 3:03 p.m.)</p> <p>18 THE VIDEOGRAPHER: The time is 3:03 p.m. and</p> <p>19 we're back on the video record.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Dr. Rosenzweig, I'd like to shift our</p> <p>22 focus a little bit to some of your other opinions.</p> <p>23 Okay?</p> <p>24 A. Okay.</p>

57 (Pages 574 to 577)

Bruce Alan Rosenzweig, M.D.

Page 578	Page 580
<p>1 Q. And the basis for your -- some of the</p> <p>2 other support for your opinion. Okay?</p> <p>3 Dr. Rosenzweig, did you also review and</p> <p>4 rely on published medical literature in reaching</p> <p>5 your opinions in this case?</p> <p>6 A. Yes.</p> <p>7 Q. Did you put together a binder of the</p> <p>8 published medical literature that you want to</p> <p>9 discuss with the jury today?</p> <p>10 A. Yes.</p> <p>11 MR. SNELL: Object; leading.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Dr. Rosenzweig, can you just briefly</p> <p>14 again -- I know we've done this before, but can you</p> <p>15 just briefly describe what your opinions are with</p> <p>16 respect to the TVT-Secur?</p> <p>17 MR. SNELL: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. In what respect?</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. The design characteristics and the</p> <p>22 complications and the efficacy, safety and efficacy</p> <p>23 of the TVT-Secur device?</p> <p>24 MR. SNELL: Same objection.</p>	<p>1 A. Yes.</p> <p>2 Q. And what opinions -- how did -- how does</p> <p>3 the medical literature support that opinion or</p> <p>4 those opinions?</p> <p>5 MR. SNELL: Objection. Go ahead.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I created a slide of the medical</p> <p>8 literature that help support my opinions regarding</p> <p>9 the design defects that are highlighted in the</p> <p>10 medical literature.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Okay. First let's go back. I think we</p> <p>13 already marked this slide, but I just want to get</p> <p>14 it pulled up again really quick. And I think it</p> <p>15 was Exhibit No. 6, I believe. Do you have 6 in</p> <p>16 front of you? Yeah, that's it right there.</p> <p>17 A. Yes. The complications due to the</p> <p>18 design defects, recurring mesh erosion, chronic</p> <p>19 pelvic pain, chronic dyspareunia, chronic urinary</p> <p>20 tract infections, recurrence of stress urinary</p> <p>21 incontinence symptoms, need for multiple surgeries</p> <p>22 which will be difficult, if not impossible to</p> <p>23 perform safely.</p> <p>24 Q. Okay.</p>
Page 579	Page 581
<p>1 BY THE WITNESS:</p> <p>2 A. The design characteristics that I talked</p> <p>3 about previously are the short, stiff, rigid</p> <p>4 laser-cut mesh that had never been used before, the</p> <p>5 arrow tip introducer that had never been used</p> <p>6 before, the fleece tips to hold the short, stiff</p> <p>7 mesh in place that had never been used before, and</p> <p>8 the introduction system that had never been used</p> <p>9 before.</p> <p>10 Because of the short, stiff, rigid mesh,</p> <p>11 it increases the risk of a chronic foreign body</p> <p>12 reaction, chronic inflammatory reaction. That</p> <p>13 leads to fibrotic bridging, scarring, excessive</p> <p>14 scarring. That leads to mesh contraction, which</p> <p>15 leads to pain.</p> <p>16 The sharp introducer drags across tissue</p> <p>17 of the vagina, which starts a greater inflammatory</p> <p>18 reaction. That leads to pain, erosion.</p> <p>19 The fleece tips do not stay in place,</p> <p>20 which leads to the mesh migration, which leads to</p> <p>21 complications and lower efficacy.</p> <p>22 Q. And were those opinions that you just</p> <p>23 expressed supported by any of the medical</p> <p>24 literature?</p>	<p>1 MR. SNELL: Going to object and move to</p> <p>2 strike. Repetition. Go ahead.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. And with respect to the design</p> <p>5 characteristics of the mesh and your opinions</p> <p>6 concerning the -- those characteristics, did you</p> <p>7 also create a slide identifying those</p> <p>8 characteristics and support provided for those</p> <p>9 opinions from the medical literature?</p> <p>10 A. Correct.</p> <p>11 Q. Now, regarding the fleece tips, how are</p> <p>12 the fleece tips, that design characteristic -- what</p> <p>13 is your opinion about that and what complications</p> <p>14 that design characteristic can lead to?</p> <p>15 A. The design characteristic of -- the</p> <p>16 defect associated with the design characteristic of</p> <p>17 the fleece tips is that the fleece tips do not hold</p> <p>18 the midurethra in place. That increases the risk</p> <p>19 of recurrent stress urinary incontinence.</p> <p>20 That also allows the mesh to migrate,</p> <p>21 which increases the chronic inflammatory reaction,</p> <p>22 chronic foreign body reaction. It increases the</p> <p>23 risk of, as I described on the previous slide,</p> <p>24 pain, pelvic pain, pain with intercourse, mesh</p>

Bruce Alan Rosenzweig, M.D.

Page 582	Page 584
<p>1 erosion, chronic urinary issues, including</p> <p>2 recurrence of stress urinary incontinence and the</p> <p>3 need for surgeries.</p> <p>4 Q. And what -- were you done? I'm sorry.</p> <p>5 I wasn't sure.</p> <p>6 A. I was --</p> <p>7 Q. I didn't mean to interrupt you.</p> <p>8 A. There are three studies in particular</p> <p>9 that talk about the fleece tips, if we could go to</p> <p>10 slide C0003.</p> <p>11 MR. SNELL: Can we hold on one second. Can we</p> <p>12 get a copy of that?</p> <p>13 MR. THORNBURGH: I just gave you a copy.</p> <p>14 MR. SNELL: No, the slide that was up, and I'm</p> <p>15 moving to strike that.</p> <p>16 MR. THORNBURGH: That was the old -- that was</p> <p>17 the old slide that you already looked at.</p> <p>18 MR. SNELL: No, it wasn't. It was something</p> <p>19 different.</p> <p>20 MR. THORNBURGH: You've got that copy right</p> <p>21 there.</p> <p>22 MR. SNELL: I don't have that. I'm not trying</p> <p>23 to be difficult. I don't have the slide that was</p> <p>24 up on the screen or the one that Dr. Rosenzweig is</p>	<p>1 get the third one.</p> <p>2 THE WITNESS: Krofta, K-r-o-f-t-a, from 2012.</p> <p>3 MR. SNELL: Thank you. Sorry.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And regarding your opinions that the</p> <p>6 mesh is too stiff and that the stiffness can cause</p> <p>7 dyspareunia and erosions, did you rely on any</p> <p>8 medical publications for that opinion or those</p> <p>9 opinions?</p> <p>10 A. Yes. A publication by Neuman from 2011</p> <p>11 and by -- by Neuman from 2011.</p> <p>12 Q. And how did the Neuman publication</p> <p>13 support your opinion?</p> <p>14 A. It showed that the short -- excuse me --</p> <p>15 the stiff rigid mesh was responsible for an</p> <p>16 eightfold increase in dyspareunia compared to a</p> <p>17 non-stiff, non-laser-cut mesh.</p> <p>18 Q. Okay. And were there any other</p> <p>19 publications that you used to support your opinion</p> <p>20 that the mesh was too short, which led to erosions</p> <p>21 or failures?</p> <p>22 A. Yes. A publication by Dr. Hinoul in</p> <p>23 2011 showed that the short mesh increased the</p> <p>24 failure rate associated with the TVT-Secur and was</p>
Page 583	Page 585
<p>1 holding.</p> <p>2 MR. THORNBURGH: Let me see it. I'm sorry.</p> <p>3 I thought I gave that to you just a</p> <p>4 moment ago.</p> <p>5 MR. SNELL: No, these are the ones I have.</p> <p>6 Fleece tips. I have this one. You gave me two of</p> <p>7 these. You can have that one back.</p> <p>8 (WHEREUPON, a certain document was</p> <p>9 marked BR-Secur Exhibit No. 7,</p> <p>10 C0003, slide of publication support</p> <p>11 for opinions.)</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And, Doctor, before we were interrupted,</p> <p>14 can you just identify the medical publications that</p> <p>15 support your opinion concerning the fleece tips?</p> <p>16 A. Yes. There's a study by Hota from 2012,</p> <p>17 a study by Hamer from 2012 and a study by Krofta</p> <p>18 from 2012 that discuss the fleece tips not holding</p> <p>19 and increasing the -- or being responsible for</p> <p>20 failures to treat stress urinary incontinence and</p> <p>21 pain with intercourse.</p> <p>22 MR. SNELL: I'm sorry. What was the last</p> <p>23 study? If the doctor could tell us that. I can't</p> <p>24 read it on here. I got Hota and Hamer. I didn't</p>	<p>1 associated with a high erosion rate.</p> <p>2 Q. And how did that publication support</p> <p>3 your opinion?</p> <p>4 A. There was an eightfold increase in the</p> <p>5 erosion rate associated with the TVT-Secur and a</p> <p>6 higher failure rate.</p> <p>7 Q. And do you have any opinions with</p> <p>8 respect to the rate of erosions associated with the</p> <p>9 TVT-Secur device?</p> <p>10 A. Yes. Based on a meta-analysis from</p> <p>11 Tommaselli in 2012, the erosion rate was found to</p> <p>12 be 15%. The highest erosion rate I've seen in the</p> <p>13 literature is in the Hota study of 19%.</p> <p>14 Q. And what -- do you have an opinion with</p> <p>15 respect to what the rate of failure is for the</p> <p>16 TVT-Secur?</p> <p>17 A. The Tommaselli meta-analysis showed that</p> <p>18 the failure rate was approximately 25% measured</p> <p>19 objectively. In a five-year study by Tommaselli,</p> <p>20 the failure rate was approximately 25%. In a 4-1/2</p> <p>21 year study by Dr. Haab, the failure rate was 70%.</p> <p>22 MR. SNELL: Do you know how to spell Haab?</p> <p>23 THE WITNESS: H-a-a-b.</p> <p>24 BY MR. THORNBURGH:</p>

Bruce Alan Rosenzweig, M.D.

Page 586	Page 588
<p>1 Q. Now, you have a binder there in front of</p> <p>2 you. Are those the medical literature or some of</p> <p>3 the medical literature that you brought with you</p> <p>4 today?</p> <p>5 A. Yes.</p> <p>6 Q. And did you review and rely on those --</p> <p>7 on the medical literature within that binder?</p> <p>8 A. Yes.</p> <p>9 Q. Is that all of the medical literature</p> <p>10 you reviewed?</p> <p>11 A. No.</p> <p>12 Q. How much medical literature,</p> <p>13 approximately how many different articles did</p> <p>14 review in coming to your opinion?</p> <p>15 A. Specifically for TVT-Secur?</p> <p>16 Q. Yes.</p> <p>17 A. To date?</p> <p>18 Q. Approximately.</p> <p>19 A. Including abstracts, not just</p> <p>20 publications?</p> <p>21 Q. Sure.</p> <p>22 A. I think in the neighborhood of 60 or so</p> <p>23 that I've reviewed to date. Possibly more.</p> <p>24 Q. And you -- what's the first article in</p>	<p>1 that the 8 centimeter tape is not appropriate for</p> <p>2 all patients and that the sharp arrowhead,</p> <p>3 quote-unquote, "scalpel-shaped tip of the inserter"</p> <p>4 is too sharp, which leads to bleeding and excessive</p> <p>5 movement from tearing of the muscle fibers.</p> <p>6 MR. SNELL: Object. Improper use of a learned</p> <p>7 treatise on direct. The witness is not allowed to</p> <p>8 read from it. The witness must internalize it.</p> <p>9 That article will not be shown on direct at trial.</p> <p>10 MR. THORNBURGH: Yeah, you can keep the</p> <p>11 article down for now.</p> <p>12 MR. SNELL: So, move to strike the answer.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Doctor, do you have any -- how does the</p> <p>15 Krofta article support your opinions concerning the</p> <p>16 TVT-Secur efficacy rate?</p> <p>17 A. It supports my opinion that there are</p> <p>18 design characteristics of the TVT-Secur device that</p> <p>19 make it unreasonably ineffective to treat stress</p> <p>20 urinary incontinence.</p> <p>21 Q. And are there any other opinions that</p> <p>22 you want to discuss that are supported by the</p> <p>23 Krofta article?</p> <p>24 A. Beside the anchoring fleece tips do not</p>
Page 587	Page 589
<p>1 your binder?</p> <p>2 A. It is P2561. It's a study from 2010 in</p> <p>3 the International Urogynecology Journal from</p> <p>4 Dr. Krofta.</p> <p>5 MR. SNELL: Can I get a copy?</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And what opinions did -- what opinions</p> <p>8 are supported by the Krofta publication?</p> <p>9 A. That there are design characteristics of</p> <p>10 the TVT-Secur device that make it unreasonably</p> <p>11 ineffective.</p> <p>12 Q. And what are those design</p> <p>13 characteristics?</p> <p>14 A. That the anchoring structure is not</p> <p>15 present, meaning that the fleece tips did not hold,</p> <p>16 and they report a one-year failure rate of</p> <p>17 approximately 50%.</p> <p>18 Q. And do you have an opinion whether a 50%</p> <p>19 failure rate at one year is a good or bad outcome</p> <p>20 for patients?</p> <p>21 MR. SNELL: Objection. Go ahead.</p> <p>22 BY THE WITNESS:</p> <p>23 A. That is a negative outcome.</p> <p>24 Another finding from the Krofta study is</p>	<p>1 hold, which increases the failure rate, the</p> <p>2 arrowhead introducer is too sharp so that it causes</p> <p>3 increased complications, therefore it is a design</p> <p>4 defect, and that the tape is too short, therefore</p> <p>5 increasing the failure rate, those are the</p> <p>6 opinions.</p> <p>7 Q. Okay. And I just want to look at the</p> <p>8 Krofta article with you really quick.</p> <p>9 And you had testified about the Krofta</p> <p>10 publication. I just want to turn attention -- we</p> <p>11 are not going to look at the entire publication.</p> <p>12 But if you turn your attention really quick to</p> <p>13 page 783.</p> <p>14 And what did the Krofta authors report</p> <p>15 concerning the rate of erosion in the TVT-Secur</p> <p>16 device compared to the TVT-O device?</p> <p>17 MR. SNELL: Object; improper use of learned</p> <p>18 treatise on direct, hearsay as to the authors'</p> <p>19 statements. No learned treatise exception to</p> <p>20 hearsay in Pennsylvania. Go ahead.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Go ahead, Doctor.</p> <p>23 A. They found a 5% rate of erosion.</p> <p>24 Q. If you look at page 783, it says, "Also,</p>

60 (Pages 586 to 589)

Bruce Alan Rosenzweig, M.D.

Page 590	Page 592
<p>1 in our study, we observed," and this is on the 2 right-hand column, "Also, in our study, we observed 3 a relatively high risk of defective healing 4 (7.3%)."</p> <p>5 The authors go on and write, "Recent 6 studies have suggested that TVT erosion ranges 7 between .04% and 1% and that the incidence of 8 vaginal erosion after TVT-O is less than 1% during 9 the first postoperative year." (As read.)</p> <p>10 It goes on to write -- to state, that 11 "There are four cases of vaginal protrusion of the 12 tape in our study."</p> <p>13 Did I read that correctly?</p> <p>14 MR. SNELL: Object. Misstates the document. 15 Also object and leading.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Did I read that correctly?</p> <p>18 A. Correct.</p> <p>19 Q. And so -- and is that where you got 20 the -- it says 4.9% was the rate of erosion in 21 their study?</p> <p>22 A. Correct.</p> <p>23 Q. Is that accurate?</p> <p>24 A. Correct. I was not counting the healing</p>	<p>1 number for Lim if there is one?</p> <p>2 A. I don't think there is one.</p> <p>3 MR. THORNBURGH: Let's go ahead and mark the 4 Lim study. And we will mark it as Exhibit 8. 5 (WHEREUPON, a certain document was 6 marked BR-Secur Exhibit No. 8, 7 Article by Lim, et al.)</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And what's the date of the Lim study?</p> <p>10 A. 2010. It's in the Australia/New Zealand 11 Journal of Obstetrics and Gynecology. I reviewed 12 and relied upon it and it --</p> <p>13 MR. SNELL: Can I get a copy before we have a 14 discussion about it?</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Did you review and rely on the Lim 17 study?</p> <p>18 A. For my opinions, yes.</p> <p>19 Q. And what opinions did the Lim study 20 support?</p> <p>21 A. It supports my opinions that there are 22 design characteristics of the TVT-Secur device that 23 make it unreasonably ineffective in treating stress 24 urinary incontinence.</p>
Page 591	Page 593
<p>1 defects. If one were to put those together, that 2 would mean that there was a 12% rate of healing 3 defects in mesh erosion.</p> <p>4 MR. SNELL: Object. Move to strike. 5 Non-responsive beyond the question.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And what symptoms were reported by 8 patients who experienced erosions in the Krofta 9 study?</p> <p>10 MR. SNELL: Object.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Discharge and dyspareunia.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Now, did Ethicon warn in its IFU the 15 risk of dyspareunia?</p> <p>16 A. No.</p> <p>17 Q. And you had talked about the briefly 18 about the Hinoul study. Is that the next article 19 in your binder?</p> <p>20 A. Actually I have the Lim study.</p> <p>21 Q. Okay. Let's talk about the Lim study, 22 then.</p> <p>23 A. This is a study by --</p> <p>24 Q. Hold on a second. What's the exhibit</p>	<p>1 Q. How does the Lim study support that 2 opinion?</p> <p>3 A. They found an objective cure rate at six 4 months of less than 60%.</p> <p>5 Q. Is that a good result or a bad result 6 for patients?</p> <p>7 MR. SNELL: Object.</p> <p>8 BY THE WITNESS:</p> <p>9 A. That is a negative result for patients 10 as it will expose them to the risk of having 11 additional surgery for their recurrence or 12 untreated stress urinary incontinence.</p> <p>13 Q. Okay. Now, are there any other opinions 14 from the Lim study -- strike that.</p> <p>15 Does -- are any of your other opinions 16 supported by the Lim study?</p> <p>17 A. Yes. That there are design 18 characteristics of the TVT-Secur device, namely, 19 the sharp arrow tip introducer, the short, stiff, 20 rigid mesh that are -- lead to complications and 21 therefore are unreasonably unsafe. They found a 22 20% groin pain and a tape erosion rate of close to 23 8%.</p> <p>24 Q. So, how does the Lim study support your</p>

61 (Pages 590 to 593)

Bruce Alan Rosenzweig, M.D.

Page 594	Page 596
<p>1 opinion concerning the design characteristics of</p> <p>2 the TVT-Secur?</p> <p>3 MR. SNELL: Objection.</p> <p>4 BY THE WITNESS:</p> <p>5 A. It shows that the design characteristics</p> <p>6 are unreasonably unsafe because of the</p> <p>7 complications that patients who have had the</p> <p>8 TVT-Secur implanted are experiencing within the</p> <p>9 first six months after implant.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And you testified that the Lim study</p> <p>12 found a rate of 20. -- 20% about. Is that what you</p> <p>13 testified to?</p> <p>14 A. Correct.</p> <p>15 Q. And how does that finding support your</p> <p>16 opinions?</p> <p>17 A. A rate of 20% of groin pain within -- in</p> <p>18 the first six months after the procedure supports</p> <p>19 my opinion that there are design characteristics of</p> <p>20 the device that make it unreasonably unsafe.</p> <p>21 Q. And --</p> <p>22 A. Including the short, stiff, rigid mesh.</p> <p>23 Q. And is a 20% rate of --</p> <p>24 MR. SNELL: Object. Move to strike.</p>	<p>1 MR. SNELL: What did we mark this?</p> <p>2 MR. THORNBURGH: We marked it as Exhibit 8.</p> <p>3 MR. SNELL: Okay. BR-Secur 8?</p> <p>4 MR. THORNBURGH: Yes. I forgot to bring the</p> <p>5 one that was marked in September I guess.</p> <p>6 MR. SNELL: I'm going to move to strike all</p> <p>7 questioning about it. I don't see it on his</p> <p>8 reliance list. Maybe I'm wrong, but that's not</p> <p>9 what -- we're not finding it. So, go ahead.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Doctor, I just want to turn your</p> <p>12 attention really quick to page 171.</p> <p>13 And there's a -- the third full</p> <p>14 paragraph, the authors write that "Although the</p> <p>15 mesh erosion rate of 7.7% in our series was</p> <p>16 considerably higher than the .4 to 4.1% reported in</p> <p>17 the TVT and TVT-O" studies or products, "it was not</p> <p>18 out of keeping with the 0.9 to 12% reported in</p> <p>19 other studies investigating the TVT-Secur</p> <p>20 procedure."</p> <p>21 Did I read that correctly?</p> <p>22 MR. SNELL: Object and leading.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes.</p>
Page 595	Page 597
<p>1 Non-responsive.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. -- groin pain a good result or good</p> <p>4 outcome for patients?</p> <p>5 A. It is a negative result for patients.</p> <p>6 Q. And did -- were there any findings from</p> <p>7 the Krofta study concerning the rate of erosions?</p> <p>8 A. The Lim study.</p> <p>9 MR. SNELL: Objection; leading.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Lim study. I'm sorry.</p> <p>12 A. It showed an approximate 8% erosion</p> <p>13 rate.</p> <p>14 Q. And is that a good result or a bad</p> <p>15 result for patients?</p> <p>16 MR. SNELL: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. That is a negative result for patients.</p> <p>19 Also, the Lim study showed that there</p> <p>20 was approximately 5% rate of tape dislodgement,</p> <p>21 which supports my opinion that the fleece tips did</p> <p>22 not hold the mesh in place and therefore the mesh</p> <p>23 could migrate and increase the risk of failure and</p> <p>24 complications.</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And what, if any, significance does that</p> <p>3 finding suggest?</p> <p>4 MR. SNELL: Object and leading, improper</p> <p>5 learned treatise, PA.</p> <p>6 BY THE WITNESS:</p> <p>7 A. That demonstrates the design defect of</p> <p>8 the TVT-Secur that makes it unreasonably unsafe.</p> <p>9 The mesh is too rigid and stiff, which increases</p> <p>10 the risk of erosion. The fleece tips do not hold</p> <p>11 the mesh in place. Therefore, the mesh migrates,</p> <p>12 which increases the risk of mesh erosion. And the</p> <p>13 sharp arrow tip introducer drags across the vaginal</p> <p>14 tissue, which disrupts the tissue and increases the</p> <p>15 risk of erosion.</p> <p>16 Q. And if you go to the "Conclusion"</p> <p>17 section really quick, can you tell the ladies and</p> <p>18 gentlemen -- of the Lim study.</p> <p>19 Can you tell the ladies and gentlemen of</p> <p>20 the jury what these researchers reported with</p> <p>21 respect to the recommendations of the TVT-Secur</p> <p>22 procedure?</p> <p>23 MR. SNELL: Object; improper learned treatise.</p> <p>24 BY THE WITNESS:</p>

62 (Pages 594 to 597)

Bruce Alan Rosenzweig, M.D.

Page 598	Page 600
<p>1 A. Based on the limited study, "we would be</p> <p>2 hesitant to recommend the TV" -- "the U</p> <p>3 configuration of the TVT-Secur procedure over its</p> <p>4 more established counterparts, the TVT and the</p> <p>5 TVT-O."</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And is there anything further you'd like</p> <p>8 to discuss from the Lim publication?</p> <p>9 A. No.</p> <p>10 MR. THORNBURGH: We have to change tape.</p> <p>11 THE VIDEOGRAPHER: The time is 3:30 p.m. This</p> <p>12 is the end of Tape 3 and we're going off the video</p> <p>13 record.</p> <p>14 (WHEREUPON, a recess was had</p> <p>15 from 3:30 to 3:47 p.m.)</p> <p>16 THE VIDEOGRAPHER: The time is 3:47 p.m. This</p> <p>17 is the beginning of Tape 4 and we are back on the</p> <p>18 video record.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. Doctor, what's the next study in your</p> <p>21 binder?</p> <p>22 A. The study by Dr. Hinoul from 2011 in the</p> <p>23 Journal of Urology.</p> <p>24 Q. And what's the exhibit number?</p>	<p>1 Q. And how does the Hinoul study support</p> <p>2 those opinions?</p> <p>3 A. On the Hinoul study, there was an</p> <p>4 approximately 25% failure rate at six months. That</p> <p>5 decreased to about a 16% rate after 12 months and</p> <p>6 there was an eight-time risk of erosion compared</p> <p>7 with the TVT-Obturator.</p> <p>8 Q. In lay terms, what does that mean?</p> <p>9 A. That there was a higher rate of failure</p> <p>10 and a higher rate of mesh protruding into the</p> <p>11 vagina for the TVT-Secur.</p> <p>12 Q. And you say "higher rate." Let's back</p> <p>13 up a little bit.</p> <p>14 The randomized controlled trial, what</p> <p>15 products did -- was Dr. Hinoul comparing?</p> <p>16 MR. SNELL: Object.</p> <p>17 BY THE WITNESS:</p> <p>18 A. The TVT-Secur with the TVT-Obturator.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. And in terms of that comparison, which</p> <p>21 product performed better?</p> <p>22 A. The TVT-Obturator.</p> <p>23 Also, one of Dr. Hinoul's conclusions</p> <p>24 was that the short 8 centimeters of mesh was too</p>
Page 599	Page 601
<p>1 A. It is P2342.</p> <p>2 Q. And did you review and rely on the</p> <p>3 Hinoul study?</p> <p>4 A. Yes.</p> <p>5 Q. And what is the Hinoul study?</p> <p>6 A. It is a prospective randomized trial</p> <p>7 comparing the TVT-Secur with the TVT-Obturator.</p> <p>8 Q. And what was the duration of that study?</p> <p>9 A. It was a one-year study.</p> <p>10 Q. Is that considered a short-term or</p> <p>11 long-term study?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. It is a short-term study. A long-term</p> <p>15 study would be a five-year study.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. And what opinions does the Hinoul</p> <p>18 randomized controlled trial support?</p> <p>19 A. The Hinoul study supports my opinion</p> <p>20 that the design characteristics of the TVT-Secur</p> <p>21 device, the short, stiff mesh with the arrow tip</p> <p>22 introducer and the fleece tips lead to the harm of</p> <p>23 an increased risk of the procedure failing and an</p> <p>24 increased risk of mesh eroding into the vagina.</p>	<p>1 short, which increased the failure rate associated</p> <p>2 with the TVT-Secur.</p> <p>3 MR. SNELL: Object. Move to strike. Reading</p> <p>4 from a learned treatise in Pennsylvania is</p> <p>5 improper.</p> <p>6 MR. THORNBURGH: He is not reading from a</p> <p>7 learned treatise.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Were you reading from the learned</p> <p>10 treatise or were you --</p> <p>11 A. Summarizing.</p> <p>12 Q. -- summarizing?</p> <p>13 A. I was summarizing.</p> <p>14 Q. Okay.</p> <p>15 MR. SNELL: Still improper -- you are not</p> <p>16 allowed to summarize the statement of another in</p> <p>17 Pennsylvania through a learned treatise.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Doctor, how does --</p> <p>20 MR. SNELL: An expert must internalize it.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Doctor, how does the Hinoul study</p> <p>23 support your opinion concerning the efficacy or</p> <p>24 lack of efficacy of the TVT-Secur product?</p>

Bruce Alan Rosenzweig, M.D.

Page 602	Page 604
<p>1 MR. SNELL: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. The Hinoul study supports my opinion</p> <p>4 that one of the design defects of the TVT-Secur is</p> <p>5 that the mesh is too short and therefore increases</p> <p>6 the risk of failure.</p> <p>7 BY MR. THORNBURGH:</p> <p>8 Q. And do you recall what the rate of</p> <p>9 erosion was in the TVT-Secur arm compared to the</p> <p>10 TVT-Obturator arm?</p> <p>11 A. Yes. 8% versus 0%.</p> <p>12 Q. And how does that finding support your</p> <p>13 opinions?</p> <p>14 A. It supports my opinions that the design</p> <p>15 defects from the TVT-Secur device, which are</p> <p>16 unreasonably unsafe, is the short, stiff, rigid</p> <p>17 mesh that is too stiff for the vagina and,</p> <p>18 therefore, leads to complications in the vagina</p> <p>19 such as mesh erosion; that the fleece tips do not</p> <p>20 hold and therefore the mesh migrates, thereby</p> <p>21 increasing the risk of erosion; and the sharp arrow</p> <p>22 introducer is too sharp and it drags across the</p> <p>23 vaginal tissue disrupting the vaginal tissue and</p> <p>24 leading to erosion.</p>	<p>1 50%, which means that the fleece tips did not hold</p> <p>2 and the mesh migrated and did not support the</p> <p>3 urethra. So, the women had a recurrence of their</p> <p>4 stress urinary incontinence.</p> <p>5 The -- this study also supports my</p> <p>6 opinion that the sharp arrow tip introducer is too</p> <p>7 sharp. It drags across the vaginal tissue which</p> <p>8 disrupts the vaginal tissue and increases the harm,</p> <p>9 including erosion and pain.</p> <p>10 Q. How does the Hota study support your</p> <p>11 opinions concerning those design characteristics?</p> <p>12 A. The findings of the study of a 19%</p> <p>13 erosion rate and an 50% failure rate.</p> <p>14 Q. And what type of study was the Hota</p> <p>15 study?</p> <p>16 A. It was a prospective randomized trial.</p> <p>17 Q. That's what we have been talking about</p> <p>18 throughout the last two days?</p> <p>19 A. Yes.</p> <p>20 Q. What we've abbreviated as RCTs?</p> <p>21 A. Correct.</p> <p>22 Q. Is this the type of study that Ethicon</p> <p>23 had originally planned on doing before they</p> <p>24 launched the TVT-Secur?</p>
Page 603	Page 605
<p>1 Q. And are there any other findings from</p> <p>2 the Hinoul study that support your opinions?</p> <p>3 A. No.</p> <p>4 Q. What's the next study in your binder?</p> <p>5 A. It's a study by Dr. Hota from 2012 in</p> <p>6 the journal Female Pelvic Medicine and</p> <p>7 Reconstructive Surgery.</p> <p>8 Q. And what's the exhibit number for the</p> <p>9 Hota study?</p> <p>10 A. P1185.</p> <p>11 Q. And when was the Hota study published?</p> <p>12 A. 2012.</p> <p>13 MR. SNELL: Thank you.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. What opinions does the Hota study</p> <p>16 support?</p> <p>17 A. The Hota study supports my opinions that</p> <p>18 there are design characteristics of the TVT-Secur</p> <p>19 device that increases harm to women that are</p> <p>20 unreasonably unsafe, including the short, stiff,</p> <p>21 rigid mesh increased the erosion rate.</p> <p>22 The erosion rate found in this study was</p> <p>23 19%. The success rate after one year was</p> <p>24 approximately 50%. So, the failure rate was almost</p>	<p>1 A. Correct.</p> <p>2 Q. And did -- and is this the study that</p> <p>3 Dr. Nilsson had recommended be done before the</p> <p>4 Secur was launched?</p> <p>5 MR. SNELL: Objection.</p> <p>6 BY THE WITNESS:</p> <p>7 A. This is the type of study that he</p> <p>8 recommended.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And how long was the Hota study?</p> <p>11 A. If I recall, the Hota study was</p> <p>12 discontinued early due to the findings of a lower</p> <p>13 success rate than they had anticipated.</p> <p>14 Q. And how long did it -- what were their</p> <p>15 final follow-up period?</p> <p>16 A. The patients were followed up for one</p> <p>17 year. However, the study was stopped early before</p> <p>18 all the patients were randomized into the study.</p> <p>19 Q. Do you recall why the study was</p> <p>20 terminated early?</p> <p>21 MR. SNELL: Objection.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Because of concerns about the higher</p> <p>24 failure rate associated with the device.</p>

64 (Pages 602 to 605)

Bruce Alan Rosenzweig, M.D.

Page 606	Page 608
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Is a 19% erosion rate a good outcome for</p> <p>3 patients?</p> <p>4 A. No, it is not.</p> <p>5 Q. Is that -- is a 19% erosion rate</p> <p>6 something that was commonly known by physicians to</p> <p>7 be associated with the Secur product?</p> <p>8 MR. SNELL: Objection.</p> <p>9 BY THE WITNESS:</p> <p>10 A. No, it was not.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Did Ethicon ever disclose to physicians</p> <p>13 that the risk of erosions associated with the TVT</p> <p>14 Secur product could be as high as 19%?</p> <p>15 MR. SNELL: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No, they did not.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Could Ethicon have disclosed that</p> <p>20 information?</p> <p>21 A. Yes.</p> <p>22 Q. Should Ethicon have disclosed that</p> <p>23 information?</p> <p>24 MR. SNELL: Object.</p>	<p>1 TVT-Secur compared to the TVT-Obturator?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. 19% versus 0%.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. And what was the reoperation rate in the</p> <p>7 TVT-Secur compared to the TVT-O?</p> <p>8 MR. SNELL: Object.</p> <p>9 BY THE WITNESS:</p> <p>10 A. 19% versus 0%.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. Is a reoperation rate of 19 -- do you</p> <p>13 have an opinion -- strike that.</p> <p>14 Do you have an opinion whether or not a</p> <p>15 19% erosion rate is unreasonably high?</p> <p>16 A. Yes, I have an opinion.</p> <p>17 Q. What's that opinion?</p> <p>18 A. Yes, that is unreasonably high.</p> <p>19 Q. Do you have an opinion whether or not a</p> <p>20 reoperation rate of 19% is unreasonably high?</p> <p>21 A. Yes, I have an opinion.</p> <p>22 Q. What's that opinion?</p> <p>23 A. It is unreasonably high.</p> <p>24 Q. Do you have an opinion one way or the</p>
Page 607	Page 609
<p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Had Ethicon performed a -- the</p> <p>5 randomized controlled trial before they launched</p> <p>6 the product, could they have learned that the risk</p> <p>7 of erosion with the TVT-Secur could be as high as</p> <p>8 19%?</p> <p>9 MR. SNELL: Objection; speculation.</p> <p>10 BY THE WITNESS:</p> <p>11 A. If they had performed a randomized</p> <p>12 controlled trial, they would have obtained data</p> <p>13 regarding the safety and efficacy of their product.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. And if we go to page 41.</p> <p>16 MR. THORNBURGH: Tom, can you blow this up.</p> <p>17 Don't worry about it.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Go to page 41, Doctor. And if you look</p> <p>20 at Table 3. Are you there?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. And what was the erosion rate --</p> <p>23 strike that. Before I go to Table 3.</p> <p>24 What was the erosion rate of the</p>	<p>1 other whether or not the risks of the TVT-Secur</p> <p>2 were outweighed -- outweighed the benefits of the</p> <p>3 TVT-Secur?</p> <p>4 A. Yes, I have an opinion.</p> <p>5 Q. What's that opinion?</p> <p>6 A. The risks outweighed the benefits.</p> <p>7 Q. And what's the basis for that opinion?</p> <p>8 A. The internal documents that I reviewed</p> <p>9 and the medical literature.</p> <p>10 Q. And is that consistent with these</p> <p>11 researchers' decisions or decision to terminate the</p> <p>12 study early?</p> <p>13 A. Correct.</p> <p>14 Q. What's the next publication in your</p> <p>15 binder?</p> <p>16 A. Publication by Dr. Andrada Hamer from</p> <p>17 the International Urogynecology Journal in 2013.</p> <p>18 MR. SNELL: Can I get a copy?</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. What's the exhibit number?</p> <p>21 A. It is P2362.</p> <p>22 Q. Can you identify P2362 to the ladies and</p> <p>23 gentlemen of the jury?</p> <p>24 A. It is a one-year prospective randomized</p>

65 (Pages 606 to 609)

Bruce Alan Rosenzweig, M.D.

Page 610	Page 612
<p>1 controlled trial comparing the TVT-Secur with the</p> <p>2 TVT.</p> <p>3 Q. Did you review and rely on the Hamer</p> <p>4 study?</p> <p>5 A. Yes.</p> <p>6 Q. And so I don't have to keep repeating</p> <p>7 that, did you review and rely on all of the studies</p> <p>8 that are in your binder?</p> <p>9 A. Yes.</p> <p>10 Q. Which we've marked -- have we marked the</p> <p>11 binder yet?</p> <p>12 MR. THORNBURGH: Let's go ahead and mark the</p> <p>13 binder as Exhibit 9.</p> <p>14 MR. SNELL: While we are doing this, move to</p> <p>15 strike the risk/benefit opinion as to violating</p> <p>16 705, PA. Go ahead.</p> <p>17 (WHEREUPON, a binder was marked as</p> <p>18 BR-Secur Exhibit No. 9: Binder</p> <p>19 containing articles relied on by</p> <p>20 deponent.)</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. What opinions does the Hamer study</p> <p>23 support?</p> <p>24 A. The Hamer study supports my opinion that</p>	<p>1 A. That demonstrates that there are design</p> <p>2 characteristics of the TVT-Secur device that make</p> <p>3 it unreasonably unsafe, including the stiff, rigid</p> <p>4 mesh, which is dangerous to the surrounding tissue</p> <p>5 and leads to erosion.</p> <p>6 Q. And was the Hamer study also a</p> <p>7 randomized controlled trial?</p> <p>8 A. Yes.</p> <p>9 Q. And, again, is this the type of study</p> <p>10 that Ethicon had planned to do before they launched</p> <p>11 the product?</p> <p>12 MR. SNELL: Object. Sorry. Object; leading.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Yes.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And can you remind the jury why Ethicon</p> <p>17 chose not to conduct a randomized controlled trial?</p> <p>18 MR. SNELL: Object.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Budget constraints.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Is that a reasonable reason for a</p> <p>23 company to choose not to do adequate studies for</p> <p>24 products it intends to sell as permanent</p>
Page 611	Page 613
<p>1 there are design characteristics of the TVT-Secur</p> <p>2 that make it unreasonably unsafe.</p> <p>3 The authors found significant</p> <p>4 complications associated with the device so that</p> <p>5 they do not recommend the use of the TVT-Secur</p> <p>6 device because of the complications associated with</p> <p>7 it, and they also found that it had a significantly</p> <p>8 lower objective cure rate than the TVT.</p> <p>9 MR. SNELL: Object. Move to strike. Violates</p> <p>10 Pennsylvania rule regarding learned treatise.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. How does -- how does the Hamer study</p> <p>13 support your opinions?</p> <p>14 A. It supports my opinions that the</p> <p>15 TVT-Secur is unreasonably unsafe and unreasonably</p> <p>16 ineffective in treating stress urinary</p> <p>17 incontinence.</p> <p>18 Q. Are there any other opinions -- do you</p> <p>19 have any other -- what other opinions, if any, does</p> <p>20 the Hamer study support?</p> <p>21 A. The Hamer study showed that there was a</p> <p>22 risk of urethral erosion of 1.4%.</p> <p>23 Q. And how does that finding support your</p> <p>24 opinion?</p>	<p>1 implantable devices?</p> <p>2 MR. SNELL: Object.</p> <p>3 BY THE WITNESS:</p> <p>4 A. No.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Are there any other opinions that are</p> <p>7 supported by the Hamer study?</p> <p>8 A. Not that I specifically recall.</p> <p>9 Q. I do want to -- if you turn with me to</p> <p>10 page 226, and you'll see on the right side of the</p> <p>11 page, the first full paragraph, the authors write,</p> <p>12 "We do not believe that the difference in cure</p> <p>13 rate - in particular, the proportion of uncured and</p> <p>14 early recurrence patients in the TVT-Secur group -</p> <p>15 can be explained by insufficient surgical skills,</p> <p>16 as the basics of both procedures are similar.</p> <p>17 Participating surgeons had broad experience in</p> <p>18 sling surgery, having performed at least 100</p> <p>19 procedures each. Moreover, pre-study training was</p> <p>20 supervised by one of the authors and aimed to</p> <p>21 standardize the operative technique before</p> <p>22 enrolling patients into the study."</p> <p>23 Did I read that correctly?</p> <p>24 MR. SNELL: Object; leading, improper use of a</p>

Bruce Alan Rosenzweig, M.D.

Page 614	Page 616
<p>1 learned treatise.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And do you have -- what does that</p> <p>6 statement by these authors indicate to you?</p> <p>7 MR. SNELL: Same objection.</p> <p>8 BY THE WITNESS:</p> <p>9 A. That there are design characteristics of</p> <p>10 the TVT-Secur that make it unreasonably unsafe or</p> <p>11 unreasonably ineffective.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. We looked at an exhibit early on in this</p> <p>14 litigation or in this deposition dating back I</p> <p>15 think to November of 2006 from David Robinson where</p> <p>16 he identified three potential explanations for the</p> <p>17 high failure rates that were being experienced by</p> <p>18 surgeons worldwide.</p> <p>19 Do you recall that exhibit?</p> <p>20 MR. SNELL: Objection; leading, misstates.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Yes.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. And do you recall one of the potential</p>	<p>1 just ask you without looking at this document.</p> <p>2 What were the conclusions of these</p> <p>3 authors?</p> <p>4 MR. SNELL: Objection; improper learned</p> <p>5 treatise.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. If you recall. Let me -- let's just do</p> <p>8 this.</p> <p>9 If you look at the "Conclusion"</p> <p>10 section -- I know we are all trying to get out of</p> <p>11 here -- you see where it says, "The main arguments</p> <p>12 for choosing TVT-Secur over TVT (less complications</p> <p>13 and need for uro" -- uri -- how do you --</p> <p>14 A. Urethrocystoscopy.</p> <p>15 Q. -- "urethrocystoscopy) are not supported</p> <p>16 by our data."</p> <p>17 Did I read that correctly?</p> <p>18 A. Yes.</p> <p>19 MR. SNELL: Objection; leading, learned</p> <p>20 treatise, improper.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Doctor, did -- do you have an opinion</p> <p>23 whether or not based on your review of the internal</p> <p>24 documents of Ethicon and the peer-reviewed</p>
Page 615	Page 617
<p>1 explanations that David Robinson had identified was</p> <p>2 surgeon technique?</p> <p>3 MR. SNELL: Object and leading.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Correct.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. And what, if anything, does the Hamer</p> <p>8 study indicate with respect to surgeon technique as</p> <p>9 being the cause of the early failure rates that</p> <p>10 were being reported worldwide?</p> <p>11 MR. SNELL: Object; improper learned treatise.</p> <p>12 BY THE WITNESS:</p> <p>13 A. The Hamer study does not find that it is</p> <p>14 the surgeon responsible for the poor outcomes</p> <p>15 associated with the TVT-Secur; that it shows that</p> <p>16 there are design characteristics that make it</p> <p>17 unreasonably unsafe or unreasonably ineffective in</p> <p>18 treating stress urinary incontinence.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. If you turn to page 227 and you see the</p> <p>21 "Conclusion" section?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And in the "Conclusion"</p> <p>24 section -- let me -- before I get there, let me</p>	<p>1 publications whether or not Ethicon's claim for</p> <p>2 choosing a TVT-Secur over a TVT, that there would</p> <p>3 be less complications and no need for cystoscopy</p> <p>4 were supported by the data?</p> <p>5 MR. SNELL: Object and violates 705, lacks</p> <p>6 specificity. Go ahead.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Not supported by this data.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. Was it -- based on your review of the</p> <p>11 overall -- your overall review of the data, both</p> <p>12 internal data of Ethicon and the publications that</p> <p>13 you've reviewed, was that claim by Ethicon</p> <p>14 supported?</p> <p>15 MR. SNELL: Same objections.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. The claim that there would be less</p> <p>18 complications?</p> <p>19 A. No.</p> <p>20 MR. SNELL: Same objections. Go ahead.</p> <p>21 BY THE WITNESS:</p> <p>22 A. That was not supported.</p> <p>23 BY MR. THORNBURGH:</p> <p>24 Q. Is there any other information from the</p>

Bruce Alan Rosenzweig, M.D.

Page 618	Page 620
<p>1 Hamer study that you'd like to discuss?</p> <p>2 A. No.</p> <p>3 Q. Before we move on to the next study, did</p> <p>4 the Hamer researchers encourage or discourage</p> <p>5 further use of the TVT-Secur product?</p> <p>6 MR. SNELL: Object; improper learned treatise.</p> <p>7 BY THE WITNESS:</p> <p>8 A. They discouraged the use of the</p> <p>9 TVT-Secur.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. And when was the Hamer study published?</p> <p>12 A. 2013.</p> <p>13 Q. And when was it first -- it looks like</p> <p>14 it was first sent to publication on what date?</p> <p>15 A. It was received from publication</p> <p>16 February of 2012.</p> <p>17 Q. How long after the Hamer researchers and</p> <p>18 scientists wrote this publication discouraging the</p> <p>19 further use of TVT-Secur did Ethicon end up</p> <p>20 discontinuing the sales of the TVT-Secur product?</p> <p>21 MR. SNELL: Objection; leading, improper</p> <p>22 learned treatise.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Approximately four months later.</p>	<p>1 compared with other single-incision slings.</p> <p>2 Q. And how does the Abdel-Fattah</p> <p>3 meta-analysis support that opinion?</p> <p>4 A. By describing the data -- a</p> <p>5 meta-analysis, as I've described before, is a</p> <p>6 publication that pools the data from all of the</p> <p>7 research that's done in a -- on a given topic and</p> <p>8 they find the best studies that they use to draw</p> <p>9 conclusions.</p> <p>10 And what they -- what the conclusions</p> <p>11 that they drew is that compared to the other</p> <p>12 midurethral slings, the TVT-Secur performed the</p> <p>13 worst compared to the other midurethral slings.</p> <p>14 MR. SNELL: Object.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Single-incision slings.</p> <p>17 MR. SNELL: Object. Move to strike. Improper</p> <p>18 use of learned treatise, hearsay of the authors.</p> <p>19 Go ahead.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Let me ask that question real quick one</p> <p>22 more time.</p> <p>23 How did the Abdel-Fattah publication</p> <p>24 support your opinions?</p>
Page 619	Page 621
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. What is the next publication that you'd</p> <p>3 like to discuss?</p> <p>4 A. It's a paper by Abdel-Fattah from</p> <p>5 European Urology 2011.</p> <p>6 Q. And what is the date of the Abdel-Fattah</p> <p>7 publication?</p> <p>8 A. 2011.</p> <p>9 MR. SNELL: Hold on. You gave me your copy.</p> <p>10 MR. THORNBURGH: Sorry.</p> <p>11 MR. SNELL: I just want a clean one.</p> <p>12 MR. THORNBURGH: I think they're all</p> <p>13 highlighted.</p> <p>14 MR. SNELL: I don't want your highlights.</p> <p>15 Go ahead. Thank you.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. What is the Abdel-Fattah publication?</p> <p>18 A. This is a meta-analysis on</p> <p>19 single-incision slings.</p> <p>20 Q. What opinion does the Abdel-Fattah</p> <p>21 meta-analysis support?</p> <p>22 A. That there are design characteristics of</p> <p>23 the TVT-Secur that make it unreasonably ineffective</p> <p>24 in treating stress urinary incontinence even</p>	<p>1 A. It supported my opinions that the</p> <p>2 TVT-Secur has design characteristics that make it</p> <p>3 unreasonably ineffective.</p> <p>4 The study showed that it -- the</p> <p>5 TVT-Secur did not even perform as well as other</p> <p>6 single-incision slings.</p> <p>7 Q. Is there any other information from the</p> <p>8 Abdel-Fattah publication that you'd like to</p> <p>9 discuss?</p> <p>10 A. No.</p> <p>11 Q. What is the next publication in your</p> <p>12 binder, which is Exhibit No. 9, right? I think so.</p> <p>13 A. Yes. This is a study by Dr. Neuman from</p> <p>14 2011.</p> <p>15 Q. And what's the exhibit number?</p> <p>16 A. It is P2309.</p> <p>17 Q. And --</p> <p>18 MR. SNELL: Give me one second just to catch</p> <p>19 up with you guys.</p> <p>20 Okay. Thank you.</p> <p>21 MR. THORNBURGH: No problem.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. And can you identify the Abdel -- sorry.</p> <p>24 Can you identify Exhibit 2309 for the</p>

68 (Pages 618 to 621)

Bruce Alan Rosenzweig, M.D.

Page 622	Page 624
<p>1 jury, please?</p> <p>2 A. Yes, it is a paper by Dr. Neuman that</p> <p>3 was published in the Journal of Minimally Invasive</p> <p>4 Gynecology in 2011.</p> <p>5 Q. What type of study was this study by</p> <p>6 Dr. Neuman?</p> <p>7 A. It is a prospective non-randomized</p> <p>8 clinical trial.</p> <p>9 Q. And what opinions does the Neuman</p> <p>10 publication support?</p> <p>11 A. The Neuman publication supports my</p> <p>12 opinion that the design characteristic of the</p> <p>13 TVT-Secur being the short, stiff, rigid, laser-cut</p> <p>14 mesh leads to the harm of pain with intercourse.</p> <p>15 Q. How does the Neuman study and those --</p> <p>16 how does the Neuman study support your opinion?</p> <p>17 A. The Neuman study found an eightfold</p> <p>18 increase in pain with intercourse associated with</p> <p>19 the short, stiff, rigid, laser-cut TVT-Secur mesh</p> <p>20 compared to a TVT-Obturator.</p> <p>21 Q. And did the Neuman study identify a</p> <p>22 reason or reasons for a higher dyspareunia rate in</p> <p>23 the TVT-Secur arm compared to the TVT-Obturator</p> <p>24 arm?</p>	<p>1 information for use the need for the complete</p> <p>2 removal or for a -- strike that.</p> <p>3 Did Ethicon disclose or inform or warn</p> <p>4 in their IFU of the potential need for subsequent</p> <p>5 surgeries to treat complications such as</p> <p>6 dyspareunia?</p> <p>7 MR. SNELL: Object.</p> <p>8 BY THE WITNESS:</p> <p>9 A. No.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Could they have warned about that?</p> <p>12 MR. SNELL: Same.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Yes.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. Should they have warned about that?</p> <p>17 A. Yes.</p> <p>18 Q. If you look at page 1 of Exhibit 2309,</p> <p>19 there is a statement by Dr. Neuman in the</p> <p>20 "Conclusion" section of the abstract that "Sexually</p> <p>21 active patients might be better referred for the</p> <p>22 TVT-O procedure because it was not followed by</p> <p>23 dyspareunia in our series."</p> <p>24 Did I read that correctly?</p>
Page 623	Page 625
<p>1 MR. SNELL: Objection; improper learned</p> <p>2 treatise, hearsay of the authors.</p> <p>3 BY THE WITNESS:</p> <p>4 A. It was concluded that the laser cutting</p> <p>5 of the short mesh in the TVT-Secur was the cause of</p> <p>6 the high rate of pain with intercourse.</p> <p>7 MR. SNELL: Move to strike the answer.</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. And does -- was there any reference by</p> <p>10 Dr. Neuman or discussion by Dr. Neuman -- strike</p> <p>11 that.</p> <p>12 Were there any findings by Dr. Neuman</p> <p>13 concerning how those patients who developed</p> <p>14 dyspareunia were treated?</p> <p>15 MR. SNELL: Object; leading.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Patients that had dyspareunia from the</p> <p>18 short, stiff mesh underwent a removal of the mesh.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. And what does that mean, Doctor?</p> <p>21 A. That they required an additional surgery</p> <p>22 to treat the complication from the defective design</p> <p>23 of the TVT-Secur.</p> <p>24 Q. Did Ethicon disclose in their</p>	<p>1 MR. SNELL: Object; learned treatise, hearsay.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes.</p> <p>4 MR. SNELL: Leading.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. Did Ethicon ever warn in their IFU or</p> <p>7 otherwise that sexually active patients may</p> <p>8 consider -- may want to consider the TVT-O</p> <p>9 procedure rather than the TVT-Secur procedure?</p> <p>10 A. No.</p> <p>11 Q. Was it common knowledge that the</p> <p>12 TVT-Secur device was associated with a greater risk</p> <p>13 of dyspareunia than the other sling products that</p> <p>14 were on the market?</p> <p>15 MR. SNELL: Object.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Is there anything else from the Neuman</p> <p>20 study that you'd like to discuss?</p> <p>21 A. No.</p> <p>22 Q. What's the next publication?</p> <p>23 A. It is an abstract by Dr. Tommaselli from</p> <p>24 2012 which summarizes the results of a</p>

69 (Pages 622 to 625)

Bruce Alan Rosenzweig, M.D.

Page 626	Page 628
<p>1 meta-analysis that was performed specifically on 2 the TVT-Secur. 3 Q. And what's the exhibit number? 4 A. P2356. 5 Q. And what opinions does the Tommaselli 6 publication support? 7 A. It supports my opinions that the 8 TVT-Secur has design characteristics that make it 9 unreasonably unsafe and unreasonably ineffective. 10 They found a 15% erosion rate and a 25% failure 11 rate. 12 Q. How did those findings support your 13 opinions, Doctor? 14 A. The -- those findings support my opinion 15 that there are design characteristics that are 16 unreasonably unsafe, including the stiff, rigid 17 mesh, the -- that increases the risk of erosion 18 into the vagina, the arrow tip introducer that 19 disrupts the vaginal tissue, which increases the 20 risk of erosion into the vagina, and the fleece 21 tips that do not hold the mesh into place, which 22 increases the risk of failure and erosion both into 23 the vagina and into other structures. 24 MR. SNELL: Move to strike. Non-responsive.</p>	<p>1 in terms of the performance of the TVT-Secur than 2 others? 3 MR. SNELL: Objection. 4 BY THE WITNESS: 5 A. Well, this meta-analysis and also one by 6 the Cochrane meta-analysis specifically looked at 7 the TVT-Secur by itself. We saw from the 8 Abdel-Fattah analysis that the TVT-Secur was 9 included in. There's another meta-analysis that 10 was done by the group by Schimpf that looked at all 11 single-incision slings together. 12 The Tommaselli was the -- specifically 13 the only one that looked specifically at the 14 TVT-Secur, though the Cochrane analysis did analyze 15 the TVT-Secur group by themselves but also looked 16 at other midurethral slings. 17 Q. Why can -- why would it be less reliable 18 to look at data concerning all of the mini-slings, 19 the pooled data, than it would be to look at the 20 metadata or meta-analysis related specifically to 21 the TVT-Secur? 22 MR. SNELL: Objection and leading. 23 BY THE WITNESS: 24 A. The -- there are two meta-analysis, both</p>
Page 627	Page 629
<p>1 BY MR. THORNBURGH: 2 Q. And, Doctor, what type of study was the 3 Tommaselli 2012 publication? 4 A. It was a meta-analysis. 5 Q. And we've talked a little bit about 6 meta-analysis and you've testified in previous 7 de bene esse depositions about what those are, but 8 could you briefly describe what a meta-analysis is. 9 A. Meta-analysis is similar to a systematic 10 review where the authors pool data from other 11 studies, categorize the studies based on the 12 quality of evidence and draw conclusions about a 13 topic based on that review of previously published 14 studies. 15 Q. And have you reviewed several 16 meta-analysis that dealt with either the TVT-Secur 17 or with mini-slings? 18 A. Yes. 19 Q. And based on your review of the -- these 20 several meta-analyses, did you find any to be more 21 authoritative or -- strike that. 22 More -- strike that. 23 Based on your review of these several 24 meta-analyses, are there any that are more reliable</p>	<p>1 the Mostafa meta-analysis and the Abdel-Fattah 2 meta-analysis, that showed that the TVT-Secur does 3 not perform both to treat incontinence and for 4 complications as well as the other single-incision 5 slings. 6 So, if one were to put -- to pool the 7 data from all single-incision slings, it might 8 decrease the -- it might dilute out the negative 9 findings from the TVT-Secur. 10 BY MR. THORNBURGH: 11 Q. And with respect to Tommaselli, do you 12 recall how many publications those authors looked 13 at in their meta-analysis? 14 A. They looked at 54 studies, including 15 both peer-reviewed literature and abstracts, but 16 divided up their data based on peer-reviewed 17 literature and had a category that just looked at 18 data from abstracts. 19 Q. And what were the findings from the 20 Tommaselli research concerning the erosion rate in 21 the published data versus the erosion rate in the 22 abstracts? 23 MR. SNELL: Objection. Also -- 24 BY THE WITNESS:</p>

Bruce Alan Rosenzweig, M.D.

Page 630	Page 632
<p>1 A. They were similar.</p> <p>2 MR. SNELL: Objection, Doctor. Also improper</p> <p>3 learned treatise in PA. Strike.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. And what was the ultimate determination</p> <p>6 by Tommaselli as to the rate of erosion?</p> <p>7 MR. SNELL: Same.</p> <p>8 BY THE WITNESS:</p> <p>9 A. It was found to be 15%. It was about</p> <p>10 16% in peer-reviewed literature and about 14% in</p> <p>11 abstracts.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Is there any other data from the</p> <p>14 Tommaselli -- Tommaselli meta-analysis that you'd</p> <p>15 like to discuss?</p> <p>16 A. No.</p> <p>17 Q. What's the next study in your binder?</p> <p>18 A. It is a meta-analysis by Dr. Mostafa</p> <p>19 published in European Urology in 2014.</p> <p>20 Q. And what's the Exhibit number for the</p> <p>21 record?</p> <p>22 A. P2281.</p> <p>23 Q. And what opinions does the Mostafa</p> <p>24 publication support?</p>	<p>1 MR. SNELL: -- in Pennsylvania.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. And what was that discussion in regard</p> <p>4 to?</p> <p>5 MR. SNELL: Same objections.</p> <p>6 BY THE WITNESS:</p> <p>7 A. The Mostafa publication described that</p> <p>8 the design characteristics that increase the risk</p> <p>9 of the TVT-Secur being ineffective in treating</p> <p>10 stress urinary incontinence was that the fleece</p> <p>11 tips did not hold and, therefore, the urethra was</p> <p>12 not supported and the risk of incontinence was</p> <p>13 higher associated with the TVT-Secur than with</p> <p>14 other single-incision slings.</p> <p>15 MR. SNELL: Move to strike. Hearsay</p> <p>16 statement.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And is that -- is that finding from</p> <p>19 Mostafa consistent with the opinions you've</p> <p>20 expressed throughout the last two days?</p> <p>21 MR. SNELL: Object.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Yes.</p> <p>24 BY MR. THORNBURGH:</p>
Page 631	Page 633
<p>1 A. It supports my opinions that there are</p> <p>2 design characteristics of the TVT-Secur that make</p> <p>3 it unreasonably ineffective in treating stress</p> <p>4 urinary incontinence.</p> <p>5 The study by Mostafa showed that the</p> <p>6 TVT-Secur does not perform as well both to treat</p> <p>7 incontinence and with complications as other</p> <p>8 single-incision slings.</p> <p>9 Q. How does the Mostafa meta-analysis</p> <p>10 support your opinion?</p> <p>11 A. It supports my opinion that there are</p> <p>12 design characteristics of the TVT-Secur that make</p> <p>13 it unreasonably unsafe and unreasonably</p> <p>14 ineffective.</p> <p>15 MR. SNELL: Objection. Move to strike.</p> <p>16 Non-responsive.</p> <p>17 BY MR. THORNBURGH:</p> <p>18 Q. And did the Mostafa publications discuss</p> <p>19 specifically any of the design characteristics of</p> <p>20 the TVT-Secur product?</p> <p>21 MR. SNELL: Object; leading, improper use of a</p> <p>22 learned treatise --</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes.</p>	<p>1 Q. And I want to point your attention</p> <p>2 really quickly to page 403 of Exhibit 2281. Are</p> <p>3 you there?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And if you -- just read -- I'm</p> <p>6 going to just discuss with you the first full</p> <p>7 paragraph on the left side under the "Introduction"</p> <p>8 section.</p> <p>9 It says, "In an early systematic review</p> <p>10 and meta-analysis in 2011, we showed that SIMS did</p> <p>11 not, at least at that stage, live up to their</p> <p>12 potential and we recommended that only" -- "they</p> <p>13 only be used within the context of research."</p> <p>14 Did I read that correctly?</p> <p>15 MR. SNELL: Object; leading, improper learned</p> <p>16 treatise.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes.</p> <p>19 BY MR. THORNBURGH:</p> <p>20 Q. And what is an SIMS or a SIMS?</p> <p>21 A. A single-incision midurethral sling.</p> <p>22 Q. And is that the same as a mini-sling?</p> <p>23 A. Yes.</p> <p>24 Q. So, is that the same as a TVT-Secur?</p>

71 (Pages 630 to 633)

Bruce Alan Rosenzweig, M.D.

Page 634	Page 636
<p>1 A. Yes.</p> <p>2 Q. Okay. And the publication goes on,</p> <p>3 "Over the last two years, about 20 randomized</p> <p>4 controlled trials (RCTs) comparing SIMS with SMUS,"</p> <p>5 which would be the synthetic midurethral slings, is</p> <p>6 that correct?</p> <p>7 A. Yes.</p> <p>8 Q. And is that the full-length slings?</p> <p>9 A. Yes.</p> <p>10 Q. "Were further reported and,</p> <p>11 additionally, a number of RCTs published their</p> <p>12 long-term follow-up."</p> <p>13 Did I read that correctly?</p> <p>14 MR. SNELL: Object; leading, hearsay, learned</p> <p>15 treatise.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. The authors go on to write that</p> <p>20 "A significant event occurred when an extensively</p> <p>21 researched SIMS (TVT-Secur) was withdrawn from</p> <p>22 clinical practice by the manufacturer, having been</p> <p>23 shown to have poor clinical outcomes at the midterm</p> <p>24 follow-up. This situation emphasizes the</p>	<p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. What's that opinion?</p> <p>5 MR. SNELL: Same.</p> <p>6 BY THE WITNESS:</p> <p>7 A. That mid- to long-term studies should be</p> <p>8 performed before a product is launched on to the</p> <p>9 market.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Is there any other information from the</p> <p>12 Mostafa meta-analysis that you wish to discuss?</p> <p>13 A. No.</p> <p>14 Q. What is the next publication in your</p> <p>15 binder?</p> <p>16 A. This is a study, a Cochrane review,</p> <p>17 which is a systematic review by Dr. Cody published</p> <p>18 in 2014.</p> <p>19 Q. And what's the exhibit number for the</p> <p>20 record?</p> <p>21 A. P2310.</p> <p>22 Q. And can you identify for the ladies and</p> <p>23 gentlemen of the jury what this publication is?</p> <p>24 A. This is a systematic review of</p>
Page 635	Page 637
<p>1 importance of mid- to long-term follow-up of new</p> <p>2 technologies before they are adopted into clinical</p> <p>3 practice."</p> <p>4 Did I read that correctly?</p> <p>5 MR. SNELL: Object; leading, hearsay, improper</p> <p>6 learned treatise.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. And do you agree with the discussion</p> <p>11 being had here by the authors in the Mostafa</p> <p>12 meta-analysis?</p> <p>13 MR. SNELL: Same objection.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yes.</p> <p>16 BY MR. THORNBURGH:</p> <p>17 Q. Do you agree with the statement --</p> <p>18 strike that.</p> <p>19 Do you agree that it is important for</p> <p>20 companies to perform mid- to long-term follow-up of</p> <p>21 new technologies before they sell those</p> <p>22 technologies to patients or to patients'</p> <p>23 physicians?</p> <p>24 MR. SNELL: Object. Same objections.</p>	<p>1 midurethral slings, and it specifically looked at</p> <p>2 the TVT-Secur as a midurethral sling.</p> <p>3 Q. And what was the date of this</p> <p>4 publication?</p> <p>5 A. 2014.</p> <p>6 Q. Now, by 2012 TVT-Secur had been</p> <p>7 withdrawn -- had been taken off -- strike that.</p> <p>8 By 2004, Ethicon was no longer selling</p> <p>9 the TVT-Secur product, is that right?</p> <p>10 MR. SNELL: Objection; misstates the evidence.</p> <p>11 MR. THORNBURGH: I think I misspoke.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. By 2014 Ethicon was no longer selling</p> <p>14 the TVT-Secur product. Is that fair?</p> <p>15 A. Correct.</p> <p>16 Q. And, obviously, this was published two</p> <p>17 years after Ethicon was no longer selling the</p> <p>18 TVT-Secur product, right?</p> <p>19 A. Correct.</p> <p>20 Q. Now, what opinions of -- are supported</p> <p>21 by this Cochrane publication?</p> <p>22 A. The opinions that the Cochrane</p> <p>23 publication supports is that the -- there are</p> <p>24 design characteristics of the TVT-Secur that led to</p>

72 (Pages 634 to 637)

Bruce Alan Rosenzweig, M.D.

Page 638	Page 640
<p>1 the risk of it being not effective for treating</p> <p>2 stress urinary incontinence.</p> <p>3 One of those design characteristics was</p> <p>4 the fleece tip mechanism didn't hold the midurethra</p> <p>5 in place, so that the harm was recurrence or poor</p> <p>6 treatment of the stress urinary incontinence.</p> <p>7 Q. And what type of study was this again?</p> <p>8 A. It was a systematic review.</p> <p>9 Q. Okay. And in this systematic review,</p> <p>10 did the authors or researchers compare the</p> <p>11 TVT-Secur to standard midurethral slings?</p> <p>12 MR. SNELL: Object; leading.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Correct.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And what were the findings by the -- by</p> <p>17 the Cochrane authors concerning the comparison</p> <p>18 between the TVT-Secur and the standard midurethral</p> <p>19 full-length slings?</p> <p>20 MR. SNELL: Object; hearsay, improper learned</p> <p>21 treatise, leading.</p> <p>22 BY THE WITNESS:</p> <p>23 A. The TVT-Secur performed inferiorly to</p> <p>24 the full-length midurethral slings in the treatment</p>	<p>1 A. It supported my opinions that there are</p> <p>2 design characteristics of the TVT-Secur that make</p> <p>3 it unreasonably unsafe. This showed that there is</p> <p>4 a higher rate of complications associated with the</p> <p>5 TVT-Secur.</p> <p>6 BY MR. THORNBURGH:</p> <p>7 Q. Is there any other data or information</p> <p>8 from the Cochrane review that you'd like to</p> <p>9 discuss?</p> <p>10 A. No.</p> <p>11 Q. Let me just look at -- look at page 2 of</p> <p>12 the Cochrane review with you.</p> <p>13 MR. SNELL: Roman numeral or numbered?</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Number 2 under the "Data Collection" --</p> <p>16 under the "Main Results" section of the -- I think</p> <p>17 the introduction -- of the abstract.</p> <p>18 Are you there?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And you see it talks about a</p> <p>21 review of the single-incision slings?</p> <p>22 MR. SNELL: Object; leading.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Correct.</p>
Page 639	Page 641
<p>1 of stress urinary incontinence.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Are there any other -- how does the</p> <p>4 Cochrane publication support any of your other</p> <p>5 opinions?</p> <p>6 A. Again, it supports my opinions that</p> <p>7 there are design characteristics that make the</p> <p>8 TVT-Secur unreasonably unsafe and unreasonably</p> <p>9 ineffective in treating stress urinary</p> <p>10 incontinence.</p> <p>11 MR. SNELL: Object. Move to strike.</p> <p>12 Non-responsive.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. And did the Cochrane analysis also look</p> <p>15 at the risk of complications of the TVT-Secur and</p> <p>16 compare those to other products?</p> <p>17 MR. SNELL: Object; leading.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Yes.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. And how did those findings from the</p> <p>22 Cochrane review support your opinion?</p> <p>23 MR. SNELL: Object; leading, improper use.</p> <p>24 BY THE WITNESS:</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. Okay. And it says that the types of</p> <p>3 single-incision slings included in this review were</p> <p>4 the TVT-Secur, the MiniArc, the Ajut, the</p> <p>5 Needleless, the Tissue Fixation System and the</p> <p>6 CureMesh.</p> <p>7 Did I read that correctly?</p> <p>8 MR. SNELL: Object; learned treatise, hearsay,</p> <p>9 leading. You left out Ophira.</p> <p>10 BY MR. THORNBURGH:</p> <p>11 Q. Sorry. And Ophira. Does that identify</p> <p>12 all of the mini-slings that were analyzed?</p> <p>13 A. Correct.</p> <p>14 Q. And if you look at the next paragraph</p> <p>15 the authors write that "Women are more likely to</p> <p>16 remain incontinent after surgery with</p> <p>17 single-incision slings than with retropubic slings</p> <p>18 such as tension-free vaginal tape."</p> <p>19 Did I read that correctly?</p> <p>20 MR. SNELL: Object; leading, improper use of</p> <p>21 learned treatise.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Yes.</p> <p>24 BY MR. THORNBURGH:</p>

Bruce Alan Rosenzweig, M.D.

Page 642	Page 644
<p>1 Q. And how, if at all, does that statement</p> <p>2 support your opinions in this case?</p> <p>3 MR. SNELL: Same objections.</p> <p>4 BY THE WITNESS:</p> <p>5 A. That there are design defects in the</p> <p>6 TVT-Secur that increased the risk of harm and</p> <p>7 increase the risk of inadequate treatment of stress</p> <p>8 urinary incontinence.</p> <p>9 BY MR. THORNBURGH:</p> <p>10 Q. The authors go on to write --</p> <p>11 MR. SNELL: Objection. Move to strike.</p> <p>12 Non-responsive.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. The authors go on to write that "The</p> <p>15 duration of the operation was slightly shorter for</p> <p>16 single-incision slings but with higher risk of de</p> <p>17 novo urgency."</p> <p>18 Did I read that correctly?</p> <p>19 A. Yes.</p> <p>20 MR. SNELL: Object.</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. How does one --</p> <p>23 MR. SNELL: Hold on.</p> <p>24 MR. THORNBURGH: Go ahead. I will give you a</p>	<p>1 BY THE WITNESS:</p> <p>2 A. That the majority of studies included</p> <p>3 the TVT-Secur that they looked at.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. The authors go on and write that</p> <p>6 "Single-incision slings resulted in higher</p> <p>7 incontinence rates compared with inside-out</p> <p>8 transobturator slings (30% versus 11%)."</p> <p>9 Did I read that correctly?</p> <p>10 MR. SNELL: Same objections.</p> <p>11 BY THE WITNESS:</p> <p>12 A. Yes.</p> <p>13 BY MR. THORNBURGH:</p> <p>14 Q. Was that a statistically significant</p> <p>15 finding?</p> <p>16 A. Yes.</p> <p>17 MR. SNELL: Same.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. And the authors again go on and write</p> <p>20 that "The adverse event profile was significantly</p> <p>21 worse, significantly" -- "specifically consisting</p> <p>22 of higher risks of vaginal mesh exposure."</p> <p>23 Did I read that correctly?</p> <p>24 MR. SNELL: Same objections.</p>
Page 643	Page 645
<p>1 standing objection.</p> <p>2 MR. SNELL: Hearsay, learned treatise,</p> <p>3 improper use, leading. Go ahead.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. How does that finding support your</p> <p>6 opinions?</p> <p>7 A. It shows that there are design</p> <p>8 characteristics of the TVT-Secur that make it</p> <p>9 unreasonably unsafe.</p> <p>10 MR. SNELL: And I think you missed my</p> <p>11 objection. I said "Same." I'm trying to be quiet</p> <p>12 and not interrupt. I'm trying to be quick too.</p> <p>13 So, go ahead.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. The authors go on and write that "Four</p> <p>16 out of five studies in the comparison included</p> <p>17 TVT-Secur as the single-incision sling."</p> <p>18 Did I read that correctly?</p> <p>19 MR. SNELL: Same objections.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Yes.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. What does that mean?</p> <p>24 MR. SNELL: Same.</p>	<p>1 BY THE WITNESS:</p> <p>2 A. Yes.</p> <p>3 BY MR. THORNBURGH:</p> <p>4 Q. Did Ethicon ever disclose in their IFU</p> <p>5 or elsewhere that the TVT-Secur was associated with</p> <p>6 a higher risk of erosions than the other meshes or</p> <p>7 mesh slings that were on the market?</p> <p>8 MR. SNELL: Object; misstates the evidence.</p> <p>9 BY THE WITNESS:</p> <p>10 A. No.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. And the authors note that "Most of these</p> <p>13 findings were derived from the trials involving</p> <p>14 TVT-Secur."</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes.</p> <p>17 MR. SNELL: Same objections.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. The authors go on to write in the next</p> <p>20 paragraph that "The duration of operation was</p> <p>21 marginally shorter for single-incision slings</p> <p>22 compared to transobturator slings, but only by</p> <p>23 approximately two minutes and with significantly</p> <p>24 heterogeneity in the comparison."</p>

74 (Pages 642 to 645)

Bruce Alan Rosenzweig, M.D.

Page 646	Page 648
<p>1 Did I read that correctly?</p> <p>2 MR. SNELL: Same objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yes.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. How, if at all, does that statement</p> <p>7 support your opinions?</p> <p>8 MR. SNELL: Same.</p> <p>9 BY THE WITNESS:</p> <p>10 A. It supports my opinions that the</p> <p>11 TVT-Secur, while touted as being a minimally</p> <p>12 invasive procedure that will decrease operative</p> <p>13 time, when looked at, would only decrease operating</p> <p>14 time by two minutes.</p> <p>15 BY MR. THORNBURGH:</p> <p>16 Q. And is that -- does that two-minute</p> <p>17 operative time in your opinion support or did it</p> <p>18 support the use of the TVT-Secur device?</p> <p>19 A. No.</p> <p>20 Q. And the authors go on to write that</p> <p>21 "The overall results showed that the TVT-Secur is</p> <p>22 considerably inferior to retropubic and inside-out</p> <p>23 transobturator slings."</p> <p>24 Did I read that correctly?</p>	<p>1 A. Yes.</p> <p>2 BY MR. THORNBURGH:</p> <p>3 Q. Are there -- is there any other</p> <p>4 information from the Cochrane review that you'd</p> <p>5 like to discuss?</p> <p>6 A. No.</p> <p>7 Q. What is the next publication that you'd</p> <p>8 like to discuss, Doctor?</p> <p>9 A. It's a study by Dr. Haab published in</p> <p>10 the European Journal of Urology in 2012 titled</p> <p>11 "TVT-Secur Single-Incision Sling After Five Years</p> <p>12 of Follow-Up: The Promises Made and Promises</p> <p>13 Broken."</p> <p>14 Q. Now, Doctor, first of all, what's the</p> <p>15 exhibit number?</p> <p>16 A. P2321.</p> <p>17 Q. And what -- can you identify again -- I</p> <p>18 didn't hear you. I was distracted a little bit.</p> <p>19 Can you identify again for the ladies</p> <p>20 and gentlemen of the jury what this study is?</p> <p>21 MR. SNELL: Objection.</p> <p>22 BY THE WITNESS:</p> <p>23 A. It is a follow-up of four and a half</p> <p>24 years of a surgeon's experience with the TVT-Secur.</p>
Page 647	Page 649
<p>1 MR. SNELL: Objection. Same objections. Go</p> <p>2 ahead.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yes.</p> <p>5 BY MR. THORNBURGH:</p> <p>6 Q. How does that statement, if at all,</p> <p>7 support your opinions?</p> <p>8 MR. SNELL: Same.</p> <p>9 BY THE WITNESS:</p> <p>10 A. It supports my opinions that there are</p> <p>11 design characteristics of the TVT-Secur device that</p> <p>12 make it unreasonably ineffective for treating</p> <p>13 stress urinary incontinence.</p> <p>14 Q. And what were the authors' conclusions?</p> <p>15 MR. SNELL: Same objections, hearsay.</p> <p>16 BY THE WITNESS:</p> <p>17 A. "TVT-Secur is inferior to standard</p> <p>18 midurethral slings for the treatment of women with</p> <p>19 stress urinary incontinence and has already been</p> <p>20 withdrawn from clinical use."</p> <p>21 BY MR. THORNBURGH:</p> <p>22 Q. Do you agree with that statement?</p> <p>23 MR. SNELL: Same.</p> <p>24 BY THE WITNESS:</p>	<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And what was the name of this study?</p> <p>3 MR. SNELL: Object.</p> <p>4 BY THE WITNESS:</p> <p>5 A. "The TVT-Secur Single-Incision Sling</p> <p>6 After Five Years of Follow-Up: The Promises Made</p> <p>7 and the Promises Broken."</p> <p>8 BY MR. THORNBURGH:</p> <p>9 Q. Doctor, what opinions does the article</p> <p>10 by Dr. Haab entitled "The Promises Made, the</p> <p>11 Promises Broken," support?</p> <p>12 MR. SNELL: Object.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Supports my opinion that there are</p> <p>15 design characteristics of the TVT-Secur device that</p> <p>16 make it unreasonably ineffective in treating stress</p> <p>17 urinary incontinence.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. How does it support those opinions,</p> <p>20 Doctor?</p> <p>21 A. That after four and a half years of</p> <p>22 follow-up, only 30% of women were cured of their</p> <p>23 stress incontinence.</p> <p>24 Q. Doctor, is this the longest -- was this</p>

Bruce Alan Rosenzweig, M.D.

Page 650	Page 652
<p>1 the longest follow-up study at the time, to your 2 knowledge? 3 MR. SNELL: Objection. 4 BY THE WITNESS: 5 A. At the time, yes. 6 BY MR. THORNBURGH: 7 Q. And we looked at -- strike that. 8 You've reviewed a number of publications 9 concerning the TVT-Secur. Is that fair? 10 A. Yes. 11 Q. And were those studies short-term, 12 mid-term or long-term studies for the most part? 13 A. For the most part they were short-term 14 studies. 15 Q. For example, we looked at the Hota 16 study, right? 17 A. Correct. 18 Q. And how long, again, was that study? 19 A. One year. 20 Q. And that's the study that you testified 21 was shut down prematurely after the efficacy or the 22 benefits of the product were outweighed by the 23 risks? 24 MR. SNELL: Objection; leading.</p>	<p>1 A. Yes. 2 BY MR. THORNBURGH: 3 Q. So, what does that mean for patients? 4 MR. SNELL: Same. 5 BY MR. THORNBURGH: 6 Q. Who are looking to short-term studies or 7 doctors -- strike that. 8 What does it mean to doctors who are 9 looking at short-term studies to determine whether 10 or not the product would be effective or safe for 11 patients? 12 MR. SNELL: Same objection. 13 BY THE WITNESS: 14 A. This is a product that is going to be 15 placed permanently in the female pelvis, on average 16 30 to 40 years in a woman that it's being placed. 17 Short-term studies will not give you the long-term 18 risks of a product that is placed inside a female 19 pelvis for the rest of their life. 20 BY MR. THORNBURGH: 21 Q. So, is a five-week study going to 22 provide you with sufficient information to know 23 what the risk is to a patient at one year? 24 A. No.</p>
Page 651	Page 653
<p>1 BY MR. THORNBURGH: 2 Q. Do you recall that? 3 MR. SNELL: Sorry. Objection; leading, 4 misstates prior testimony. 5 BY THE WITNESS: 6 A. Correct. 7 BY MR. THORNBURGH: 8 Q. In your -- to your knowledge based on 9 your review of the medical publications, over time, 10 do patients experience more complications -- 11 MR. SNELL: Object; leading. 12 BY MR. THORNBURGH: 13 Q. -- from the TVT-Secur? 14 MR. SNELL: Leading. 15 BY THE WITNESS: 16 A. Yes. 17 BY MR. THORNBURGH: 18 Q. And over time, based on your review both 19 of the internal Ethicon company documents and the 20 peer-reviewed publications, does the TVT-Secur 21 become less effective? 22 MR. SNELL: Object; leading, also violates 23 705. 24 BY THE WITNESS:</p>	<p>1 Q. Is a one-year study going to provide you 2 with sufficient data to inform you what the risk is 3 to a patient at two years? 4 MR. SNELL: Objection. 5 BY THE WITNESS: 6 A. No. 7 BY MR. THORNBURGH: 8 Q. Is a two-year study sufficient to 9 provide you with information as to the risk to 10 patients at ten years? 11 MR. SNELL: Same. 12 BY THE WITNESS: 13 A. No. 14 BY MR. THORNBURGH: 15 Q. And what about the or how does the Haab 16 study, "The Promises Made and Promises Broken," 17 support your opinions in this case? 18 MR. SNELL: Object. Move to strike the title. 19 Improper opinion by experts, hearsay. Go ahead. 20 BY THE WITNESS: 21 A. It supports my opinion that there are 22 design characteristics of the TVT-Secur that make 23 it unreasonably ineffective in treating stress 24 urinary incontinence.</p>

76 (Pages 650 to 653)

Bruce Alan Rosenzweig, M.D.

Page 654	Page 656
<p>1 BY MR. THORNBURGH:</p> <p>2 Q. And when was the Haab study published?</p> <p>3 A. 2012.</p> <p>4 Q. And what were the findings from Dr. Haab</p> <p>5 in his long-term study?</p> <p>6 MR. SNELL: Object; improper learned treatise.</p> <p>7 Sorry, doctor. Go ahead.</p> <p>8 BY THE WITNESS:</p> <p>9 A. At four and a half years, only 30%,</p> <p>10 slightly over 30% of women were cured of their</p> <p>11 stress incontinence.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. And what was the failure rate, then, for</p> <p>14 the TVT-Secur at 4.5 years?</p> <p>15 MR. SNELL: Same.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Almost 70%.</p> <p>18 BY MR. THORNBURGH:</p> <p>19 Q. Is that a good result for patients,</p> <p>20 Doctor?</p> <p>21 MR. SNELL: Object.</p> <p>22 BY THE WITNESS:</p> <p>23 A. No.</p> <p>24 BY MR. THORNBURGH:</p>	<p>1 Q. What's the next publication, Doctor?</p> <p>2 A. It is a publication by Dr. Nilsson from</p> <p>3 the International Urogynecology Journal in 2005.</p> <p>4 Q. And what is the Exhibit number?</p> <p>5 A. P2282.</p> <p>6 Q. And what opinions does the Exhibit P2282</p> <p>7 support?</p> <p>8 A. That the TVT-Secur was inadequately</p> <p>9 studied prior to launch of the device.</p> <p>10 Q. And who was the author of this</p> <p>11 publication?</p> <p>12 A. Dr. Nilsson.</p> <p>13 Q. And do you recall what Dr. Nilsson</p> <p>14 reported in this publication, P2282?</p> <p>15 MR. SNELL: Object; improper learned treatise.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Yes, that new devices to treat stress</p> <p>18 urinary incontinence should be studied and the</p> <p>19 information analyzed prior to a new device being</p> <p>20 put on the market.</p> <p>21 MR. SNELL: Move to strike. Summary/reading.</p> <p>22 BY MR. THORNBURGH:</p> <p>23 Q. I just want to turn your attention</p> <p>24 really quick to page 468.</p>
Page 655	Page 657
<p>1 Q. Based on your review of Ethicon's</p> <p>2 internal documents and the peer-reviewed</p> <p>3 publications, what were the promises made that were</p> <p>4 broken by Ethicon?</p> <p>5 MR. SNELL: Object; leading, 705 violation.</p> <p>6 Same objections.</p> <p>7 BY THE WITNESS:</p> <p>8 A. That the safety and efficacy of the</p> <p>9 TVT-Secur would be similar or equivalent to the</p> <p>10 full-length slings.</p> <p>11 BY MR. THORNBURGH:</p> <p>12 Q. And was that -- did that claim by</p> <p>13 Ethicon, which we saw early on in their internal</p> <p>14 documents, did that claim bear out to be true or</p> <p>15 false?</p> <p>16 MR. SNELL: Object and leading.</p> <p>17 BY THE WITNESS:</p> <p>18 A. The literature showed that that was not</p> <p>19 the case.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Are there any other -- is there any</p> <p>22 other information in the Exhibit P2321 that you</p> <p>23 wish to discuss?</p> <p>24 A. No.</p>	<p>1 You'll see the last sentence in the last</p> <p>2 paragraph states, "It is a waste of both public and</p> <p>3 private resources to launch poorly documented new</p> <p>4 treatment concepts and it is especially wrong for</p> <p>5 the women suffering from stress urinary</p> <p>6 incontinence to become the subjects of experimental</p> <p>7 efforts without ethical approval and written</p> <p>8 informed consent."</p> <p>9 Did I read that correctly?</p> <p>10 MR. SNELL: Objection; improper learned</p> <p>11 treatise as well.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yes.</p> <p>14 BY MR. THORNBURGH:</p> <p>15 Q. Do you agree with that statement by</p> <p>16 Dr. Nilsson?</p> <p>17 MR. SNELL: Same.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Yes.</p> <p>20 BY MR. THORNBURGH:</p> <p>21 Q. Do you agree that it is a waste of both</p> <p>22 public and private resources to launch studies --</p> <p>23 to launch products that have not been properly</p> <p>24 tested?</p>

77 (Pages 654 to 657)

Bruce Alan Rosenzweig, M.D.

<p style="text-align: right;">Page 658</p> <p>1 MR. SNELL: Same.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yes.</p> <p>4 BY MR. THORNBURGH:</p> <p>5 Q. Do you agree that it is wrong for women</p> <p>6 suffering from stress urinary incontinence to</p> <p>7 become the subjects of experimental, untested</p> <p>8 products?</p> <p>9 MR. SNELL: Object and same as before.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yes.</p> <p>12 BY MR. THORNBURGH:</p> <p>13 Q. Is there anything else from the 2015</p> <p>14 Nilsson publication that you'd like to discuss?</p> <p>15 A. No.</p> <p>16 MR. THORNBURGH: Take a break.</p> <p>17 MR. SNELL: Sure.</p> <p>18 THE VIDEOGRAPHER: Okay. The time is 4:53</p> <p>19 p.m. and we're going off the video record.</p> <p>20 (WHEREUPON, a recess was had</p> <p>21 from 4:53 to 5:06 p.m.)</p> <p>22 THE VIDEOGRAPHER: The time is 5:06 p.m. This</p> <p>23 is the end of Tape 4. It's also the end of</p> <p>24 Volume 2 of the deposition of Dr. Bruce Rosenzweig</p>	<p style="text-align: right;">Page 660</p> <p>1 I, CORINNE T. MARUT, C.S.R. No. 84-1968,</p> <p>2 Registered Professional Reporter and Certified</p> <p>3 Shorthand Reporter, do hereby certify:</p> <p>4 That previous to the commencement of the</p> <p>5 examination of the witness, the witness was duly</p> <p>6 sworn to testify the whole truth concerning the</p> <p>7 matters herein;</p> <p>8 That the foregoing deposition transcript</p> <p>9 was reported stenographically by me, was thereafter</p> <p>10 reduced to typewriting under my personal direction</p> <p>11 and constitutes a true record of the testimony</p> <p>12 given and the proceedings had;</p> <p>13 That the said deposition was taken</p> <p>14 before me at the time and place specified;</p> <p>15 That the reading and signing by the</p> <p>16 witness of the deposition transcript was agreed</p> <p>17 upon as stated herein;</p> <p>18 That I am not a relative or employee or</p> <p>19 attorney or counsel, nor a relative or employee of</p> <p>20 such attorney or counsel for any of the parties</p> <p>21 hereto, nor interested directly or indirectly in</p> <p>22 the outcome of this action.</p> <p>23 It was requested before completion of</p> <p>24 the deposition that the witness, BRUCE ALAN</p> <p>ROSENZWEIG, M.D., have the opportunity to read and</p> <p>sign the deposition transcript.</p> <p style="text-align: center;">CORINNE T. MARUT, Certified Reporter</p> <p>(The foregoing certification of this</p> <p>transcript does not apply to any</p> <p>reproduction of the same by any means, unless under</p> <p>the direct control and/or supervision of the</p> <p>certifying reporter.)</p>
<p style="text-align: right;">Page 659</p> <p>1 and we're going off the video record.</p> <p>2 (WHEREUPON, at 5:06 p.m. the</p> <p>3 videotaped de bene esse deposition</p> <p>4 of BRUCE ALAN ROSENZWEIG, M.D. was</p> <p>5 adjourned, to be reconvened at 9:00</p> <p>6 a.m., on Sunday, July 16, 2017.)</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 661</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over</p> <p>4 carefully and make any necessary corrections. You</p> <p>5 should state the reason in the appropriate space on</p> <p>6 the errata sheet for any corrections that are made.</p> <p>7 After doing so, please sign the errata</p> <p>8 sheet and date it.</p> <p>9 You are signing same subject to the</p> <p>10 changes you have noted on the errata sheet, which</p> <p>11 will be attached to your deposition.</p> <p>12 It is imperative that you return the</p> <p>13 original errata sheet to the deposing attorney</p> <p>14 within thirty (30) days of receipt of the</p> <p>15 deposition transcript by you. If you fail to do</p> <p>16 so, the deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>